FEASIBILITY AND PSYCHOMETRIC EVALUATION OF THE STUDIO ALTERAZIONI CUTANEE STOMALI (SACS™) INSTRUMENT FOR ASSESSMENT OF PERISTOMAL SKIN LESIONS IN CHILDREN

by

Seraphine Chepkemoi Kapsandoy

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STATEMENT OF DISSERTATION APPROVAL

The following faculty members served as the supervisory committee chair and members for the dissertation of Seraphine Chepkemoi Kapsandoy.

Dates at right indicate the members' approval of the dissertation.

Katherine Sward, Chair	10/15/2014 Date Approved
Lauri Linder, Member	10/15/2014 Date Approved
Nancy Staggers, Member	10/15/2014 Date Approved
Bob Wong, Member	10/15/2014 Date Approved
Earl Downey, Member	10/15/2014 Date Approved

and by Patricia Morton, Chair/Dean of the Department/College/School of Nursing

and by David B. Kieda, Dean of The Graduate School.

ABSTRACT

Peristomal skin lesions are common following stoma surgery. However, there is wide variability in how those lesions are documented. The purpose of this study was to evaluate psychometric properties and feasibility of use for the Studio Alterazioni Cutanee Stomali (SACS™) instrument. Content validity was previously evaluated. This study extends that work by examining use in pediatrics, use by parents and bedside nurses, and by evaluating reliability and validity.

The study was guided by the Donabedian Structure-Process-Outcome framework and psychometric theory. Data collection included questionnaire, direct observation, and rating of lesion photographs. Participants were 64 parents of children who had undergone stoma surgery, 64 bedside nurses, and 10 wound nurses, who simultaneously assessed the child's skin lesion. There were 73 lesions in 65 children, with 292 direct observations and 40 photographs.

Findings supported use of the SACS™ instrument in pediatrics. The instrument was feasible for parent and nurse use. Most parents (98%) were willing to use the instrument at home. Intrarater reliability was acceptable when ratings were grouped into clinically relevant categories (78-85% agreement for lesion severity). There was strong evidence of interrater reliability, with intraclass correlation > 0.91. The contrasted groups approach supported construct validity, demonstrating that the instrument could distinguish between lesions of known severity, and that parents and bedside nurses, who

have less stoma experience, rate lesions in a similar manner to each other, and differently than wound experts. Most important clinically, there was strong evidence of decision validity; the instrument was able to discriminate between lesions that needed to be seen in clinic and those that could be safely treated at home. When there was disagreement, raters consistently erred on the side of safety, rating lesions as more severe than the expert, which would have resulted in the child being assessed by a clinician.

Limitations included a single setting with limited number of wound nurses, convenience sampling, and predominantly Caucasian population. Strengths included standardized methodology and strong basis in the theoretical framework. The study demonstrated that the instrument can be used in the pediatric population to document peristomal skin lesions, which should facilitate clinical decisions and communication.

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DEFINITION OF TERMS

Stoma. A stoma is a surgically created opening through the abdominal wall, into the gastrointestinal tract, for diverting lumenal contents into an external pouch, or for providing direct access for nutritional support (enteral nutrition therapy). In this study, stoma is used to refer to: (a) ostomies (any opening for diverting lumenal contents), (b) gastrostomy or opening into the stomach, which usually includes placement of a gastric or gastro-jejunal tube for feeding.

Peristomal Skin Lesion. A peristomal skin lesion is abnormal, discolored, or decreased skin tissue around the stoma. In this study, peristomal skin lesion refers to peristomal skin breakdown, skin ulcers, and other skin conditions and complications around the stoma.

Parent. For this study, the term parent will be used generically to refer to any adult who has primary responsibility for the home care of a child who has a stoma. The term includes parents, guardians, and other caregivers.

Bedside Nurse. A bedside nurse is one who has been assigned a patient/s and provides direct patient care to that patient/s in the hospital or clinic setting.

WOC Nurse Expert. For this study, the term WOC nurse expert will be used to refer to a nurse who has been certified as a wound, ostomy, and continence specialist by the Wound, Ostomy and Continence Nursing Certification Board (WOCNCB) and has practiced as a WOC nurse at Primary Children's Hospital (PCH).

Wound/ET Nurse. For this study, the term wound/ET nurse was used to refer to a nurse who provides wound, ostomy, and continence services to patients, but did not hold WOC nurse certification at study commencement.

Gold Standard. A gold standard is the best, most reliable known thing of its type; used as a benchmark. An analogous term is reference standard: something considered by an authority as a basis of comparison.

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CHAPTER 1

INTRODUCTION

Clinical Issue

Peristomal skin lesions are an important clinical problem in the pediatric inpatient and outpatient setting. Despite major advances in stoma care, peristomal skin lesions are common after stoma surgery (Colwell, 2004; Cottam, Richards, Hasted, & Blackman, 2007; Friedman, Ahmed, Connolly, Chait, & Mahant, 2004; Naiditch, Lautz, & Barsness, 2010; Nybaek & Jemec, 2010). The number of stoma patients is known to be growing. However, the precise rate of complications cannot be clearly determined (Ratliff, Scarano, & Donovan, 2007).

Peristomal skin lesions cause increased healthcare costs and a reduced quality of life. Skin lesions can mean repeat hospital visits and increased resource utilization. Peristomal skin integrity affects how ostomy patients adapt to their new lives (Barreire, Oliveira, Kazama, Kimura, & Santos, 2003; Bosio et al., 2007; English & Claessens, 2008) and can predict the total quality of life for adults with stomas (Pittman et al., 2008; Wu, Chau, & Twinn, 2007). Compromised peristomal skin is likely to have similar effects on children with stomas.

Early intervention for altered skin integrity is crucial. Healthcare outcomes including cost-effectiveness and quality of life can be improved through prompt identification and management of peristomal skin complications. Wound, ostomy, and

continence (WOC) nurses are wound or enterostomal therapy (wound/ET) nurses who have been certified as experts in the care and management of peristomal skin lesions (Erwin-Toth, 2000; Rolstad & Netsch, 2004). However, the number of wound/ET nurses and WOC nurse experts is limited, and most routine care is provided by bedside nurses and family caregivers (Beitz et al., 2010).

Need for a Peristomal Skin Assessment Tool

The first step in managing peristomal skin lesions is assessment. However, there is a lack of consensus about how to describe peristomal lesions. Determining complication rates in the literature is further challenged by differences in study design, populations, and timing of measurements. Information about peristomal skin can be difficult to locate in nursing documentation, and is recorded in a highly variable manner. The lack of consensus can lead to inconsistent and unreliable data that may hamper quality care delivery, coordination, quality improvement, and evidence-based practice efforts. Variability in documentation may cause difficulties in clinical care, with potential miscommunication between providers (Colwell & Beitz, 2007; Salvadalena, 2008).

A conceptual content analysis of charts from 10 patients who had undergone stoma surgery in a pediatric hospital illustrated this wide variability and revealed differences between bedside and wound/ET nurse charting (Kapsandoy, 2014). Figure 1 shows the number of different (unique) terms used by bedside and wound/ET nurses to describe the condition of the peristomal skin. Issues common to paper documentation, regardless of topic, were identified in stoma charting, such as poor readability and handwriting, misspellings, inconsistent location for the charting, and the use of ambiguous phrases and symbols. Issues specific to peristomal skin documentation

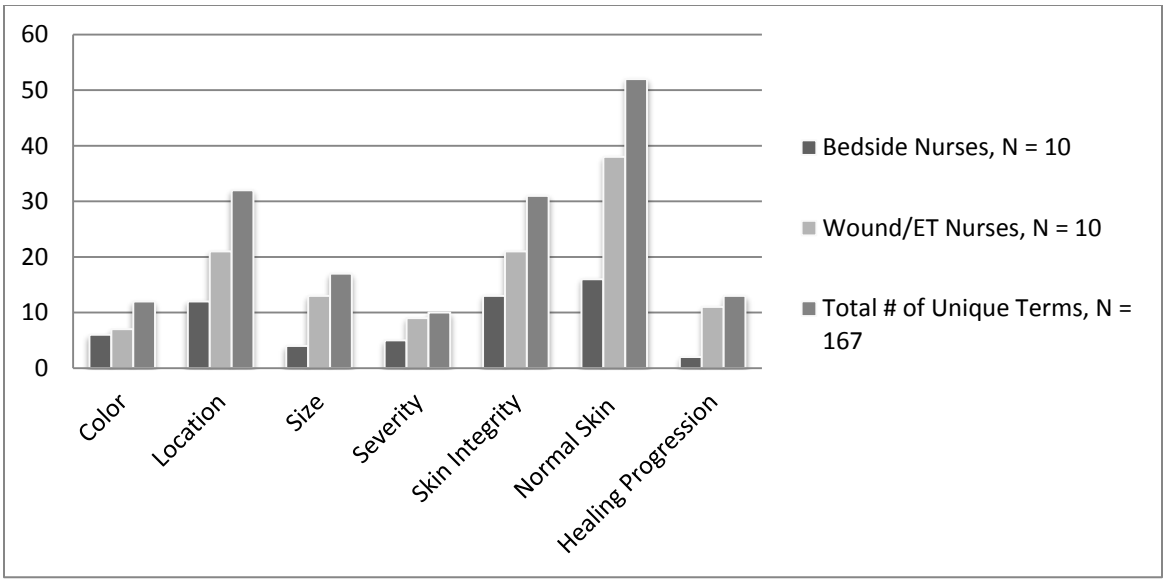


Figure 1. Wound/ET and bedside nurse peristomal skin descriptors.

were identified, including (a) multiple locations in the paper chart for charting peristomal skin, (b) stoma was charted but there was no description of the peristomal skin, (c) multiple ways to state "normal" skin, (d) multiple descriptors for lesion color, location, size, severity, and skin integrity, and (e) difficulty in tracking the healing progression.

Studio Alterazioni Cutanee Stomali (SACS™) Instrument

Consistent definitions and a reliable and valid peristomal skin lesion measurement method are needed (Salvadalena, 2008). The Studio Alterazioni Cutanee Stomali (SACS™) instrument was developed to establish a standardized language and an objective method for assessing peristomal skin condition. The instrument content validity was assessed in Italy and the U.S. with a U.S. population overall content validity index of 0.94 out of 1.0 (Beitz et al., 2010). (Content validity examines the items on the instrument to determine the extent to which all applicable facets of the domain of interest are represented [Waltz et al., 2010]).

Content validity is of primary concern during instrument development. It is important to evaluate diverse aspects of instrument validity and reliability in each new context of use (Waltz et al., 2010). The prior content validity assessment focused on adult patients. Since skin structure and physiological functions mature over time, pediatric skin may be more vulnerable to the development of skin lesions than adult skin, particularly during infancy (Fluhr et al., 2010). Despite potential differences in risk between children and adults, the skin assessment process is the same for both (Mansen & Gabiola, 2014). Therefore, the previous content validity findings are likely to be applicable to the pediatric population. However, other psychometric assessments should still be conducted before widespread use of the instrument in the pediatric setting. In addition, the instrument was only evaluated when using stoma experts (Beitz et al., 2010; Beitz & Ho, 2010). Use by other clinicians or parents has not been evaluated.

Clinical Need at Primary Children's Hospital

Since the formation of the Wound/Enterostomal Therapy (wound/ET) department at Primary Children's Hospital (PCH), the number of stoma patients referred to the team has steadily increased. A review of telephone logs for 2011 showed that the Wound/ET nurses received an average of three calls a day from parents seeking advice on management of peristomal skin lesions (Kapsandoy, S.K., 2003, unpublished raw data). Parents were typically instructed to bring their child to the clinic but often, after arrival, the problems were found to be minor. Therefore, parents were making unnecessary trips into the clinic, resulting in avoidable direct and indirect costs associated with care. Nurses stated they routinely tell parents to bring the child into clinic because they are uncertain of how well the parent's description actually reflects the affected skin.

Statement of the Problem

One way to address uncertainty and lack of consensus in relation to how peristomal skin lesions are described is by using a standardized assessment tool. The Studio Alterazioni Cutanee Stomali (SACS™) instrument (Appendix A) has been proposed as a standardized tool for peristomal skin assessments. However, data collection instruments should be evaluated before use in a new context (Donabedian, 2005; Waltz et al., 2010). While the SACS™ instrument has been assessed for content validity, other forms of validity and reliability have not yet been reported. No literature reports the use of this instrument in pediatrics. The feasibility of SACS™ instrument use by anyone other than a wound, ostomy, and continence/enterostomal therapy (WOC) nurse expert has not been reported (Beitz et al., 2010; Beitz & Ho, 2010).

Some parents and nurses have suggested that sending a photograph of the child's stoma, perhaps via an email message, might alleviate some of the communication gap. However, the feasibility of transmitting stoma photographs is also unknown. The previous assessments (Beitz et al., 2010; Beitz & Ho, 2010) were based on photographs, but whether a photograph can provide sufficient information to inform the decision about a clinical visit is unknown.

Study Purpose and Aims

The SACS™ instrument has been proposed as a potential data collection tool, which would support assessments of a child's peristomal skin in an acute care children's hospital (PCH). The purpose of this study was to evaluate the SACS™ instrument feasibility and psychometric properties prior to use in this context. The study aims were to determine:

1. The extent to which it is feasible for parents and nurses to use the SACS™ instrument to rate a child's peristomal skin.
2. The evidence of reliability when the SACS™ instrument is used by parents and nurses to describe a child's peristomal skin lesion.
3. The evidence of validity when the SACS™ instrument is used by parents and nurses to describe a child's peristomal skin lesion.

Significance

There is a need to reduce variability in the measurement and clinical documentation of peristomal skin lesions (Kapsandoy, 2014). More meaningful nursing data can be achieved with structured documentation and standardized languages (Dochterman et al., 2005; Keenan, Falan, Heath, & Treder, 2003). It is important to consider human factors, including the level of difficult of using the tool (Staggers, Weir, & Phansalkar, 2008). Such a tool would support documentation consistency. It could enhance clinical descriptions and reduce assessment variation (Jemec & Wulf, 1997; Nybaek, Knudsen, Laursen, Karlsmark, & Jemec, 2010).

The study was a first step in examining the extent to which the SACS™ instrument could be used by parents and bedside nurses, and to evaluate it in pediatrics. The study extends previous psychometric assessments beyond content validity to other validity aspects (construct validity, decision validity) and to reliability. A standardized instrument that can be used in a pediatric setting by nurses and parents to describe peristomal skin would help support communication. Moreover, reduced variability in clinical documentation would support development of the evidence base for peristomal skin lesion treatment, management, and prevention in children with stomas.

Theoretical Framework

Avedis Donabedian's classic healthcare quality framework (Structure-Process-Outcome, SPO, 1997), which was first proposed in the 1960s, remains a predominant model for examining healthcare from a systems perspective. It provided the overarching conceptual framework to guide this study.

The study evaluated a peristomal skin lesion assessment instrument. Because it was an instrument evaluation, measurement theory and instrument evaluation (psychometrics) provided the methodological and analytical framework for the research. In particular, the study was guided by the concepts and definitions for measurement in nursing and health research presented by Waltz, Strickland, and Lenz (2010).

Donabedian Structure-Process-Outcome Framework

Levels of quality

Donabedian (1997) argued that healthcare quality is assessed at four levels: (a) care provided by clinicians (clinician performance), (b) amenities, (c) care implemented by the patient/family, and (d) care received by the community. *Clinician performance* consists of two elements: technical performance and interpersonal performance. Technical performance involves the knowledge and judgment to determine care strategies and the skills to implement them. Quality of technical performance is judged by comparing observed behavior to the current best practice. Interpersonal performance refers to the communication that occurs between the patient (or in the case of children, the parent) and the clinician. Both parties must exchange information for care to be successful (Donabedian, 1997). *Amenities* are the qualities of the healthcare setting such as privacy, convenience, quiet, and comfort. The responsibilities for these amenities lie

with the providers, if in private practice, or institutional owners and managers for organizations. *Care implemented by the patient and the family* comprises the third level of the framework. The success, or failure, of care is not exclusively dependent on providers. It is also dependent on patients and their families. For example, lack of adherence to a prescribed treatment regime can cause treatment failure (Donabedian, 1997). *Care received by the community* is the fourth level. The community includes providers as well as recipients of care. This level of assessment examines factors that affect an entire community such as access to care (Donabedian, 1997).

Key elements: structure, process, outcome

Donabedian (1997) suggested the key elements that affect quality of care are structure, process, and outcome. Structure and process interact and lead to an outcome. *Structure* describes the care setting. This includes material resources such as money, facilities, and equipment, human resources such as variety, qualification, and number of personnel, and organizational attributes such as reimbursement methods. *Process* involves the activities that constitute giving and receiving healthcare. Examples include, but are not limited to, assessment, diagnosis, treatment, and educational interventions.

Donabedian noted that some healthcare outcomes are unmistakable and easy to measure (such as death), but many healthcare concepts are less well defined, and cannot be directly observed. Processes of care, including the information obtained through physical examination (patient assessments) are salient concepts to examine in healthcare research (Donabedian, 2005). *Outcome* represents the changes in an individual's characteristics as a result of the care received. Examples of outcomes are change in health status, behavior, knowledge, and satisfaction (Donabedian, 1997).

Evaluating assessment instruments

The psychometric properties of the assessment instruments are pertinent metrics for evaluating data collection tools within the SPO framework (Donabedian, 2005). Donabedian noted that methods for collecting information are of crucial importance. Documentation is commonly accepted as an indirect representation of assessment information. Donabedian described healthcare documentation in the context of the SPO framework. He emphasized the importance of evaluating instrument reliability and validity, and the challenges presented by bias and error (Donabedian, 2005). These evaluations are currently framed as *psychometric* evaluations.

Psychometrics

Background

Knowledge about people, processes, events, and objects is acquired through observation. Making sense of these observations often requires *measurement,* which is a process of assigning values to quantify and describe the characteristics (attributes) of objects or people (Waltz, Strickland, & Lenz, 2010). *Instrumentation* refers to the process of selecting or developing tools for measuring an attribute.

Psychometrics emerged as a subspecialty of science involving the theory and technique of psychological measurement, that is, the development and testing of instruments for assessing psychological and social phenomena or constructs (DeVellis, 2003; Nunnally & Bernstein, 1994). The field has expanded to encompass assessment and measurement of many types of constructs across many fields. Psychometric methods to evaluate data collection instruments are crucial in healthcare fields such as nursing (Waltz et al., 2010).

Many of the constructs and phenomena of interest are complex and subjective, requiring human judgment and interpretation, and therefore are not directly quantifiable. A *concept* is an abstraction, or mental model, representing the construct or phenomenon. The concept is *operationalized* (made measurable) by means of a tool or assessment instrument which, in turn, may contain multiple items known as attributes that describe facets of the construct. Psychometrics examines the *adequacy of concept operationalization* (Waltz et al., 2010). In simpler terms, psychometrics provides a scientific approach to evaluating the extent to which a data collection instrument is appropriate for use and for a particular purpose.

Psychometric evaluation does not assess the tool in isolation but the tool as it is used in a particular context. The evaluations provide evidence about the extent to which various criteria have been demonstrated. Evidence is accrued over time and in various contexts. The tool should be evaluated each time it is used in a new context (Waltz et al., 2010).

Psychometric evaluation of assessment instruments

Two essential criteria for psychometric evaluations are reliability and validity (Donabedian, 2005; Waltz et al., 2010). Reliability refers to consistency of scores, ratings, or categorizations that are assigned to observations using the assessment tool. Validity refers to evaluations about the extent to which the tool is useful for the intended purpose (Waltz et al., 2010). The two criteria are related. Reliability is a necessary prerequisite for validity (a tool must be reliable to be valid), but is not sufficient for validity on its own. For example, consider a bathroom scale that always measures 10 pounds light. Measurements might be consistent (reliable) but incorrect (not valid). Other

criteria may also be important in evaluating a data collection instrument. These include pragmatic considerations about the ability to use the instrument, such as ease of use, simplicity, or cost (feasibility), the extent to which data collection fits with workflow, the perceived usefulness for accomplishing a task (utility), the scale or level of detail (precision), and other criteria (Waltz et al., 2010).

Theoretical Framework as Operationalized for This Study

The SACS™ instrument could influence two of Donabedian's (1997) assessment levels, clinician performance and care implemented by patient and family. The elements of interest were identified as shown in Figure 2. One of the strengths of the Donabedian framework is that it is applicable at multiple levels including evaluating tools for data collection (Donabedian, 2005). Psychometric evaluation of the instrument reflects the interplay between structure and process elements, i.e., the instrument as used in a particular context.

For this instrument evaluation, the overarching concept and focus of measurement was peristomal skin integrity, defined as intact and undamaged skin (dermis or

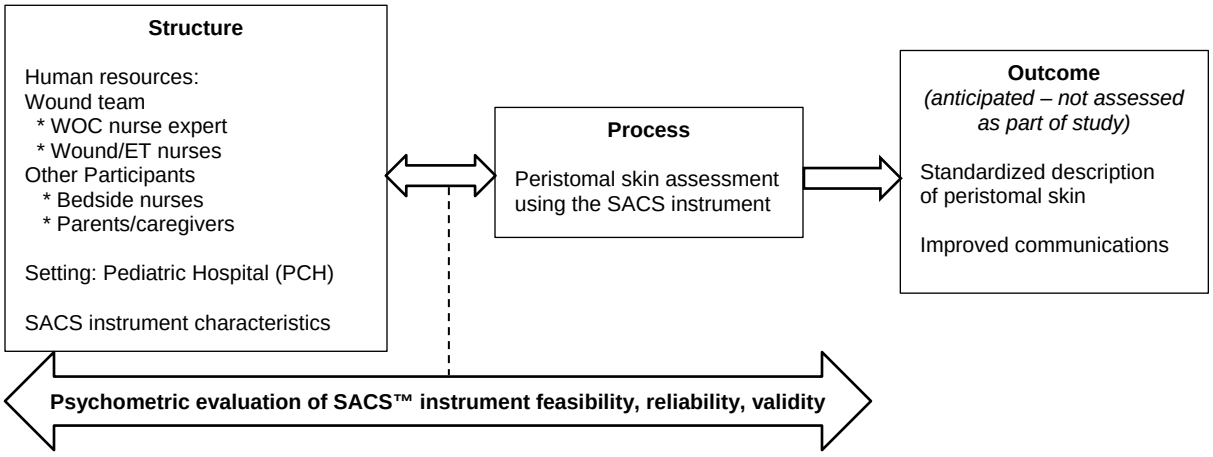


Figure 2. The theoretical framework for this study.

epidermis). This is reflected in the nursing diagnosis known as *impaired skin integrity* (NLM, 2010). The context of use was a pediatric acute care hospital with parents, bedside nurses, and wound team nurses as the observers who used the SACS™ instrument. This context of use was identified as *structure* in the theoretical framework.

Donabedian indicated that data collection tools have aspects of both structure and process (Donabedian, 2005). The characteristics of the SACS™ instrument (including the quality of the pictures and descriptions of lesions on the instrument) were identified as structure elements. The use of the instrument to rate (categorize) a child's peristomal skin was identified as a process. Study aims of examining feasibility of use, and estimates of instrument reliability and validity, reflect the interplay between the instrument characteristics (structure) and instrument use (process).

The anticipated outcome from using the SACS instrument is a standardized description of peristomal skin. Ultimately, standardized descriptions used over time are expected to support communication about a child's peristomal skin. Because this was a single point in time study, communication and other longitudinal outcomes were not evaluated.

Assumptions

This study was based on several assumptions. The first assumption was that the peristomal skin condition is an objective reality that can be measured. The second assumption was that the participants would rate the peristomal skin condition based on observation apart from their perception or feelings. It was assumed that the WOC nurse expert was a model of excellence and would objectively and consistently use the SACS™ instrument to rate the peristomal skin condition. The nurse expert ratings based on direct

observation were assumed to represent the "correct" description of the skin lesion. The final assumption was that the general pediatric population will be similar to the one chosen for the study because the hospital serves pediatric patients from five states.

CHAPTER 2

REVIEW OF THE LITERATURE

The literature review outlines the clinical focus of the study by defining stoma and peristomal skin lesions. Unique aspects of pediatric skin physiology are described that provide additional context about the clinical problem. A case is presented for standardizing nursing documentation of peristomal skin lesions. The standardized peristomal skin assessment instrument used in this study is then described. This study was an instrument evaluation so concepts and procedures for instrument evaluation (psychometrics) are presented.

Stoma and Peristomal Skin

Treatment of some digestive system diseases or bowel trauma involves the surgical creation of an opening into the body through the abdominal wall. This opening is referred to as a stoma (Merriam-Webster Inc., 2007). This study focused on two specific types of abdominal stomas: those involving the enteric system (intestines), called an *ostomy*, and those involving the gastric system (stomach), referred to as *gastrostomy*.

An ostomy is a surgically created opening in the abdominal wall with part of the intestine brought through the opening for the purpose of diverting body waste into an external pouch (Colwell, Goldberg, & Carmel, 2004). This type of stoma is usually created when the natural channels of bowel waste elimination can no longer fulfill their

roles due to disease or trauma. Types of ostomies may be further named by their location within the intestines. Names include cecostomy, colostomy, duodenostomy, ileostomy, jejunostomy, and appendicostomy.

A gastrostomy refers to a surgically created opening into the stomach for purposes of nutritional support (enteral nutrition therapy) (Shellito & Malt, 1985). A tube is inserted into the stoma through the skin and the stomach wall and directly into the stomach or upper part of the small intestine to facilitate feeding. Bowel motility may be compromised or slowed due to disease or after abdominal surgery causing abdominal distention. This may lead to serious complications, including nausea, vomiting, and aspiration. In these cases, the gastrostomy tube may be used to remove abdominal pressure, decrease abdominal distention, and to speed up the return of bowel function (Mack et al., 2004; Williams & Leslie, 2004, 2005). Similar to ostomies, gastrostomies may be further described by the location of the distal end of the feeding tube. For example, gastrostomy tube (G-tube) is a shorter tube that ends in the stomach while a gastrojejunal/gastroenteric tube (GJ-tube) is longer and ends in the small intestine. Gastrostomies can also be described by the type of surgical procedure used to create and place the tube. For example, a percutaneous endoscopic gastrostomy or jejunostomy tube (PEG or PEJ) is placed using an endoscopic surgical procedure.

Regardless of whether or not the stoma is for drainage, feeding, or other purposes, and regardless of whether or not a tube is placed within the stoma, the area of skin surrounding the stoma is referred to as the peristomal skin. For purposes of this study, the term *stoma* will be used generically to describe all abdominal stomas.

Peristomal Skin Lesions in Pediatric Populations

While a consensus exists that the number of patients with stomas continues to grow, the precise number of children with stomas is difficult to ascertain. Hellman and Lago (1990) estimated that in the United States, approximately 1.5 million patients had undergone stomal surgery, with 100,000 new cases added each year. Currently, it is estimated that there are between 450,000 to 800,000 ostomy patients in the United States and that the number will continue to grow at an annual rate of 3% (Turnbull, 2003). The use of gastrostomy as a method of providing enteral nutrition has increased and become widely accepted (Wollman & D'Agostino, 1997; Wollman, D'Agostino, Walus-Wigle, Easter, & Beale, 1995). Additionally, as gastrostomy surgical techniques continue to improve, so does morbidity. Studies demonstrate low morbidity and high success rates of the radiologic gastrostomy or percutaneous nonendoscopic techniques (Barron et al., 2000; Campos & Marchesini, 1999; Chait et al., 1996; Krishnamurthy et al., 2007; Shellito & Malt, 1985; Wales et al., 2002). It is also reasonable to conclude that the number of children undergoing ostomy and gastrostomy surgery will also continue to increase.

Despite major advances in stoma care, alterations in peristomal skin and tissue integrity are one of the most frequent inherent problems following stoma surgery. Although studies demonstrate a high rate of peristomal skin lesions in stoma patients, the actual numbers vary from study to study and are difficult to discern particularly in the pediatric population. Peristomal skin infections in gastrostomy patients have been reported to range between 5.4% and 30% (Lynch & Fang, 2004) and 10% and 70% in ostomy patients (Ratliff, 2010). Differences in how patients were subset and how

complications were described contributed to the uncertain rates. Cottam et al. (2007) reported that 34% of patients had skin lesions within 3 weeks of surgery and center-specific rates ranged from 9 to 96%. Friedman et al. (2004) separately reported each type of stoma problem but did not specify a time following surgery, reporting 25% of patients with skin infection and 2% with subcutaneous abscess. Ratliff et al. (2005) reported 16% of patients having skin lesions within 2 months of surgery and later reported 47% of patients with peristomal skin lesions (Ratliff, 2010). Similar variability was seen in other studies: Duchesne et al., 2002 reported rates of 14-36%; Giacomini et al., 2009 reported 64% in the first week after surgery, 45% in weeks 1 to 4, and 48% between 1 and 5 months; Hellman & Lago, 1990 (37% to 79% depending on type of ostomy); Lachter et al., 2002 (51%, age range 12 to 91 years); Lyon et al., 2000 (73%, self-report based on a survey, ages not specified); Naiditch et al., 2010 separately reported granulation tissue, drainage, candidiasis, cellulitis, and fistula; Richbourg, Thorpe, & Rapp, 2007.

Preservation of peristomal skin integrity affects how ostomy patients adapt to their new lives (Barreire et al., 2003; Bosio et al., 2007; English & Claessens, 2008). Previous research suggests that difficulty adjusting, stoma site leakage, and skin lesions can predict the total quality of life scores for adults with stomas (Pittman et al., 2008; Wu et al., 2007). Compromised peristomal skin is likely to have similar effects on children with stomas with reduced quality of life, interference with activities of daily living, and subsequent psychosocial distress. Studies also suggest that the involvement of enterostomal (ET) nurses in the care and management of patients with stomas can help prevent and decrease peristomal skin lesions (Duchesne et al., 2002; Hellman & Lago, 1990; Richbourg, Thorpe, & Rapp, 2007).

Peristomal skin lesions can result in repeated hospital visits and increased utilization of healthcare resources to meet patient care needs (Jemec & Nybaek, 2008; Naiditch et al., 2010). The Cleveland Clinic Stoma Registry reported that 26% of ostomy visits were due to irritant dermatitis skin lesions as a result of chemical destruction of the skin from effluent. Other types of skin lesions such as mechanical trauma, folliculitis, pseudoverrucous lesions, candidiasis, and allergic contact dermatitis accounted for 4% to 6% of visits (Erwin-Toth, Stricker, & Rijswijk, 2010).

The quality of life and care cost-effectiveness for patients who have undergone stoma surgery can be significantly improved through prompt identification, immediate management of peristomal skin lesions, and the incorporation of preventive measures (Erwin-Toth, 2000). However, there are barriers to self-care prevention. Shorter hospital stays, an increase in laparoscopic surgeries, and the decrease in reimbursements for outpatient and home health services has led to fewer opportunities to fully educate patients and parents on stoma care and problem-solving techniques. Families of children with gastrostomy tube feedings experience high levels of burnout and stress (Goldberg, Barton, Xanthopoulos, Stettler, & Liacouras, 2010).

Skin Physiology in Pediatrics

The majority of literature on peristomal skin lesions is based on adult research and findings are commonly extrapolated to the pediatric population. Although the skin structure in children is similar to that of adults, many functions are not fully developed in children. Skin structure and function are of particular importance following stoma surgery because infants and children are more susceptible than adults to percutaneous vulnerability issues (Mancini, 2004; Nikolovski, Stamatas, Kollias, & Wiegand, 2008).

The skin is a complex and dynamic organ responsible for multiple functions including protection, thermoregulation, hydration, immune-surveillance, sensory perception, and hormone synthesis (Cartlidge, 2000; 2008). The skin's ability to act as a barrier between the host and the chemical, biological, and physical environment is of particular importance. Skin physiologic parameters are routinely assessed through the examination of stratum corneum (SC) thickness, skin pH, SC hydration (conductance and capacitance), transepidermal water loss (TEWL), and percutaneous absorption (Elsner, 1998; Rook & Burns, 2010). Current studies indicate that, although the structure of the skin may be fully present at infancy, functional skin adaptation may not be completely developed until later in life with varying time points in particular (Chiou & Blume-Peytavi, 2004; Fluhr et al., 2010; Hoeger & Enzmann, 2002; Michel, L'Heureux, Auger, & Germain, 1997).

Stratum Corneum Thickness

The skin's barrier function mainly resides in the stratum corneum (SC). It is the most superficial skin layer and the foundation of the epidermis (McKinley & O'Loughlin, 2008; Michel et al., 1997). Varied results have been reported in relation to SC thickness in infants (Chiou & Blume-Peytavi, 2004). Fairley and Rasmussen (1983) compared stratum corneum (SC) thickness from the abdominal skin of infants (< 3 months), children (3 months and 11 years), and adults (17 to 46 years). The comparison was done using a filar micrometer eyepiece to examine histologic sections acquired at autopsy. Results showed no significant statistical differences between any of the groups (p = 0.0746), suggesting that infants, children, and adults have similar SC thickness.

Other studies conducted using different methodologies such as ultrasound, fluorescence spectroscopy, video microscopy, and confocal laser scanning microscopy, suggest that infants have a thinner SC (Evans & Rutter, 1986; Nikolovski et al., 2008; Stamatas, Nikolovski, Luedtke, Kollias, & Wiegand, 2010; Tan, Statham, Marks, & Payne, 1982). In a study comparing the skin microstructure in vivo, Stamatas et al. (2010) obtained skin samples from the lower thigh of 20 healthy infants (3 – 24 months) and their mothers (25 – 43 years) using fluorescence spectroscopy, video microscopy, and confocal laser scanning microscopy. Results showed that infant SC and epidermis were thinner than those of adults by 30% and 20%, respectively. Corneocytes were found at 20%, and 10% of granular cells were smaller in infants compared to adults. This indicates that infants have a more rapid cell turnover. These results suggest that the differences observed in the adult and infant skin microstructure may be contributing factors in functional differences.

In preterm neonates, the SC and epidermis layers are thinner, suggesting potential different skin physiologic properties between pre- and full-term neonates (Chiou & Blume-Peytavi, 2004). The SC begins to develop around a 24-week gestation and is well defined at around a 34-week gestation (Afsar, 2010; Cartlidge, 2000; Fluhr et al., 2010). Postnatally, the development of the skin in preterm infants is dramatically increased, and by 2 to 3 weeks, the epidermal layer is similar to that of a full-term infant (Cartlidge, 2000; Nikolovski et al., 2008). The time required for preterm infants' skin to adapt postnatally is said to be dependent upon gestational age, with severely premature infants requiring a longer time (Afsar, 2010).

The SC is produced by keratinocytes cell proliferation and differentiations

(Michel et al., 1997; Rook & Burns, 2010). In a study conducted to examine if donor age influenced the microscopic structure and functional properties of differentiating skin (the SC), Michel et al. (1997) compared newborn, child, and adult skin keratinocytes cells using an in vitro model for the evaluation of skin properties (Michel, Germain, Belanger, & Auger, 1995), a method developed by the researchers. Results showed that newborn skin contained more stem cells when compared to that of a child and adult. However, no age-related differences were seen at the microscopic level in the differentiated tissues. Lipid density and profile were found to be similar, and percutaneous absorption did not vary with age. This suggests that functional barrier properties of the skin did not vary with age and were similar in newborns, children, and adults.

Current evidence suggests that, although at birth, full-term infants seem to have similar SC to adults, the development of infant skin may not be fully complete (Chiou & Blume-Peytavi, 2004; Fluhr et al., 2010). Evidence suggests that infants born prematurely (< 34 weeks gestational age) exhibit underdeveloped barrier function (Fluhr et al., 2010). However, research also indicates that, regardless of gestational age, the skin at birth undergoes a dramatic adaptation and development so that even premature infants possess a SC similar to infants at approximately 2 to 5 weeks of age (Fluhr et al., 2010).

Skin pH

Stratum Corneum (SC) acidity (acid mantle) plays an important role in the skin's ability to provide bacterial, chemical, and mechanical resistance (McKinley & O'Loughlin, 2012; Rook & Burns, 2010). Current evidence suggests that the skin pH in children is similar to that of adults (Chiou & Blume-Peytavi, 2004). However, the skin pH in neonates (< 1 month) has been reported to be significantly higher than adults. It

decreases later in infancy to adult levels (Chiou & Blume-Peytavi, 2004; Fluhr et al., 2010). This higher pH level may predispose neonates and infants to more peristomal skin lesions and infections.

Yosipovitch, Maayan-Metzger, Merlob, and Sirota (2000) examined skin barrier functions in different anatomical sites from 44 healthy newborn full-term infants (37-42 weeks gestational age) during their first 2 days of life. The transepidermal water loss (TEWL), SC hydration, and skin surface pH measurements were obtained from the infants' soles, back, abdomen, palms, forearm, forehead, and inguinal regions. Skin pH in all body parts was found to be significantly higher in infants compared to adults ($p < 0.01$). Other studies show that after birth, skin pH tends to decrease and stabilize to levels similar to that in adults.

Hoeger and Enzmann (2002) conducted a prospective study examining skin physiologic parameters in 202 healthy Caucasian full-term neonates and infants. Measurements of the skin pH, surface roughness, SC hydration (capacitance), and epidermal desquamation from four body regions (forehead, cheek, gluteal, and volar forearm) were collected during the first 3 months after birth at the following intervals: 3 days, 4 weeks, and 12 weeks. Results showed that during the first 3 months of life, the skin pH decreased ($p < 0.001$) in all regions.

For children (> 1 year of age), current evidence suggests that skin pH is similar to that of adults. Fluhr, Pfisterer, and Gloor (2000) compared skin physiologic parameters using samples obtained from the volar forearm of children and their parents. The study was conducted under identical climatic conditions using noninvasive bioengineering methods. A total of 44 children (1-6 years) and 44 adults were examined for TEWL,

color, erythema, pH, cuteanous blood flow, SC hydration (capacitance and conductance), and dynamic SC hydration (hygroscopicity and water-holding capacity). Skin pH results showed no significant difference between children and adults.

In summary, skin pH values have been shown to be high (alkaline) after birth with a decreasing trend, reaching normalized adult ranges during the neonatal period (between 1 and 4 weeks) and remaining stable and similar to those of adults later in infancy (Fluhr et al., 2010; Hoeger & Enzmann, 2002).

Stratum Corneum Hydration

Stratum Corneum (SC) hydration (skin moisture) is routinely assessed by measuring the electrical properties of the skin surface: capacitance and conductance (Fluhr et al., 2010; Rook & Burns, 2010). The skin surface desquamation process, morphology, and cornification process are all influenced by the SC water content (Chiou & Blume-Peytavi, 2004).

SC hydration is decreased in full-term neonates at birth as compared to adults, and increases with postnatal age (Chiou & Blume-Peytavi, 2004; Fluhr et al., 2010). Yosipovitch et al. (2000) reported SC hydration in infants to be significantly different from adults during the first 2 days of life. SC hydration was lower in the forehead ($p < 0.01$), abdomen ($p < 0.05$), and back ($p < 0.05$), and higher in the forearm ($p < 0.001$) and palms ($p <0.01$). On the second day, significantly higher values were observed in the inguinal region ($p <0.05$), and lower values for the forearms ($p < 0.05$) and palms ($p < 0.005$). Other studies also demonstrate that SC hydration increased ($p < 0.05$) after birth with no significant changes between 30 and 90 days in healthy full-term neonates and infants (Hoeger & Enzmann, 2002). SC hydration in preterm infants less than 30 weeks

gestational age has been reported to be significantly higher when compared with infants greater than 30 weeks gestational age (Okah, Wickett, Pickens, & Hoath, 1995).

Compared to adults, infant SC is significantly more hydrated during the first year of life. Nikolovski et al. (2008) compared the water storing capacity and transport properties of the SC between 124 infants (3-12 months) and 104 adults (14-73 years) by measuring capacitance, transepidermal water loss (TEWL), and absorption-desorption rates. Results showed that infants had significantly higher skin conductance and water content compared to adults.

There may be physiologic skin parameter differences between children in different age groups when compared to adults. Fluhr et al. (2000) reported no significant statistical differences between children ages 1 to 6 years of age and adults in capacitance, conductance, and water-holding capacity. However, there were significant statistical differences with hygroscopicity (children's skin had a lower ability to absorb and retain moisture, making the skin more vulnerable to injury). Akutsu et al. (2009) compared SC functional properties of skin acquired from the cheek, extensor forearm, and flexor forearm between 32 healthy children (10-14 years) and their mothers (30-48 years). Results showed that children had significantly lower SC hydration ($p < 0.05$).

Transepidermal Water Loss (TEWL)

The moisture inherent within the skin layer itself is only one aspect of fluid management controlled by skin. Barrier function is generally assessed by measurement of transepidural water loss (TEWL) and is useful in the determination of epidermal maturation (Chiou & Blume-Peytavi, 2004; Fluhr et al., 2010; Rook & Burns, 2010). Impeded barrier function is indicated by a high rate of TEWL and is a sign of an

immature stratum corneum (Chiou & Blume-Peytavi, 2004; Fluhr et al., 2010). Current research suggests that although there are differences between full-term infants and adults in TEWL, the differences have not been found to be statistically significant, with full-term infants (6 – 8 g/m2/h) being similar to adults (10 g/m2/h) TEWL (Chiou & Blume-Peytavi, 2004).

Yosipovitch et al. (2000) reported that, compared to adults, the TEWL in infants was significantly lower in the soles, palms, and forehead ($p < 0.001$) and higher in the forearm ($p < 0.0001$). TEWL values in the soles, palms, and forehead were significantly higher on the first day of life compared to the second day, with values being higher in the palms, forehead, and inguinal regions. TEWL and Stratum Corneum (SC) hydration were also found to be correlated in infants, but not in adults. Nikolovski et al. (2008) reported water loss rates were higher in infants (3-12 months) and had greater variation compared to adults (14-73 years). The infant SC was found to exhibit higher capacitance, TEWL, and absorption-desorption rates.

Compared to full-term newborns, preterm newborns have been found to have markedly higher TEWL (Afsar, 2010; Chiou & Blume-Peytavi, 2004; Fluhr et al., 2010). At birth, compared to full-term neonates whose permeability barrier function is fully developed, permeability barrier function in preterm newborns is underdeveloped (Fluhr et al., 2010). Cartlidge (2000) demonstrated that preterm infants (< 30 weeks gestational age) have an impeded epidermal barrier postnatally, as well as if there is damage due to involvement of disease or trauma to the cutaneous (Cartlidge, 2000).

Studies with children suggest that there are TEWL differences between different age groups. Fluhr et al. (2000) reported no statistical differences with TEWL measured

from the volar forearm between children 1 to 6 years of age and adults. Akutsu et al. (2009), however, reported decreased TEWL values acquired from the cheek, extensor forearm, and flexor forearm in children 10 to 14 years old compared to adults 30 to 48 years. TEWL values were decreased in the forearm and increased in the cheeks with increasing age. This indicates that SC barrier function characteristics may be dependent on age.

In TEWL and percutaneous water absorption, SC maturity is thought to occur anywhere between 30 to 37 weeks (Harpin & Rutter, 1983; Kalia, Nonato, Lund, & Guy, 1998). Other investigators have reported that TEWL levels in full-term infants are similar to adults, and therefore, full-term infants have functionally mature SC at birth (Nikolovski et al., 2008). Supporting evidence suggests that in full-term infants, a slight increase in TEWL values can be observed during the first few hours of birth. They then decrease to values similar to those in healthy adults (Fluhr et al., 2010; Hoeger & Enzmann, 2002). Evidence also suggests that barrier function, water-holding, and transport properties of infant SC continue to develop through the first year of life (Nikolovski et al., 2008).

Evidence also indicates that conductance (SC hydration) in infants is low at birth and increases thereafter (Hoeger & Enzmann, 2002; Yosipovitch et al., 2000). Other results indicate that SC water holding and transport properties are in continuous flow in contrast with adults (Nikolovski et al., 2008). With full-term infants the SC hydration values start out low at birth and continue to rise until approximately 2 weeks after birth to normalization with similar values observed in adults (Fluhr et al., 2010; Hoeger & Enzmann, 2002).

Percutaneous Absorption

Percutaneous drug absorption is an indicator of an effective Stratum Corneum (SC) (Chiou & Blume-Peytavi, 2004; Rook & Burns, 2010). Percutaneous absorption is influenced by barrier skin properties, surface-area-to-body-weight ratio, postnatal age, blood flow rate, and physical and chemical characteristics of drugs (Chiou & Blume-Peytavi, 2004; Mancini, 2004). Studies have demonstrated a direct correlation between risk and young age, which is related to infants having a higher surface area-to-weight ratio (Mancini, 2004). The hazards of percutaneous absorption are well documented. There are toxicity and fatality reports related to alcohol, aniline dyes, iodine, lindane, hexachlorophene, and boric acid (Chiou & Blume-Peytavi, 2004; Mancini, 2004). Although studies indicate that preterm infants are at a greater risk of percutaneous toxicity, full-term infants, older infants, and children have also been demonstrated to be at risk (Chiou & Blume-Peytavi, 2004; Mancini, 2004). Concomitantly, cyanosis attributed to metahemoglobinemia after application of prilocaine, which is found in eutectic local anesthetic cream (2.5% lidocaine and 2.5% prilocaine), has been reported in pre- and full-term infants as well as children (Mancini, 2004).

Skin Physiology Summary

The literature is inconclusive concerning similarities and differences in skin physiology parameters between children and adults. The timeline as to when infants and children acquire a fully mature Stratum Corneum (SC) remains unclear. Findings vary regarding whether the skin structures and functions of children and adults are comparable and vary regarding the rate of maturation of skin functions. Studies suggest possible skin physiologic differences between children in different age groups and adults. These

varying results may be attributed to the various methodologies used in the measurement of skin physiology parameters. Despite varying evidence, some studies continue to suggest that pediatric skin may be more vulnerable than adult skin.

Findings demonstrate that infants and children are more susceptible to percutaneous vulnerability (Mancini, 2004; Nikolovski et al., 2008). Treatment and prevention of peristomal skin lesions often involves application of topical agents such as powders and pastes to the peristomal skin. Percutaneous absorption of topically applied agents and the potential for resultant systemic toxicity are important considerations in children with stomas.

The variation in rates of development and skin maturity in the pediatric population underscores the importance of examining interventions, treatments, and instruments used in the prevention and management of peristomal skin lesions and stomal conditions including complications. Most stoma literature is based on adult research extrapolated to the pediatric population, but it is not clear that this extrapolation is appropriate. Given the inconclusive and varied findings regarding differences and similarities in skin physiology parameters between the pediatric and adult population, perhaps it is not appropriate.

Studies evaluating gender differences with skin surface pH remain inconclusive. Additional research is needed in this area. Studies addressing ethnic differences are deficient in the pediatric population and warrant attention. Obtaining a clear understanding of the development and functional properties in all pediatric age groups can help provide insight into the assessment and treatment of peristomal skin lesions in the pediatric population.

Standardizing Peristomal Skin Lesion Nursing Documentation

Given the inconclusive literature regarding pediatric peristomal skin lesions and skin physiology parameters between children and adults, the development of high-quality evidence in the pediatric population becomes a significant need. Even types of peristomal skin lesions and complication rates are difficult to discern with reports varying from 6% to 70% (Colwell & Beitz, 2007; Salvadalena, 2008). Comparing stomal and peristomal complications, including lesions, across studies has been problematic due to the lack of consensus in definitions and terminology, differences in study design, populations, and timing measurements (Colwell & Beitz, 2007; Salvadalena, 2008).

In a systematic review, Salvadalena (2008) identified 21 studies published between 1990 and 2007 that measured the incidence of stoma and peristomal complications. Salvadalena (2008) concluded that major problems preventing meta-analysis among these studies included the variability in study designs and the absence of operational definitions.

Providing patient care usually involves a multidisciplinary approach with information exchange and communication as essential factors for patient safety and quality care (Simpson, 2003). Communication requires that the receiver understand the communication and interpret it as having meaning. The meaning perceived by the receiver must be the same as the meaning intended by the sender for communication to be effective (Chambers, 2001; Saba & McCormick, 2006). To represent a concept, that is, a unit of thought, such as the “idea” of what a peristomal skin lesion is, terms (words and phrases) are used to describe the phenomenon (Saba & McCormick, 2006). A set of terms is a terminology.

Effective communication is optimized through the use of standardized terminologies, communication formats, and conventions for describing complex concepts such as peristomal skin lesions (Saba & McCormick, 2006). Nursing records are the foremost source of information used by general practitioners for follow-up treatment as well as by care unit managers for statistical and care evaluation purposes (Tornvall & Wilhelmsson, 2008; Tornvall, Wilhelmsson, & Wahren, 2004). This makes nursing documentation, as a source of communication, that much more critical.

Problems with Nonstandardized Documentation

Healthcare policy makers, providers, and consumers are increasingly demanding high quality care while simultaneously controlling costs. The growing emphasis on evidence-based practice (EBP), as a means to meet the twin goals of quality and efficiency, has propelled crucial discussions about using healthcare data to determine best practices among various healthcare disciplines (Saba & McCormick, 2006). Documentation is often a benchmark by which the quality of care can be assessed and measured (Donabedian, 1997; Quigley, Mathis, & Nodhturft, 1994; Whited et al., 2010). Inadequate documentation and lack of structure with nursing care documentation are common problems (Friberg, Bergh, & Lepp, 2006; Hyde et al., 2005; Idvall & Ehrenberg, 2002; Irving et al., 2006). Documentation deficiencies may hamper the continuity of care for patients and may create safety and quality consequences (Bjorvell, Thorell-Ekstrand, & Wredling, 2000; Black, Taunton, Thomas, & Krampitz, 1989; Mashru & Lant, 1997).

Law, Akroyd, and Burke (2010) conducted a case study with stoma care in a hospital ward to examine the role of nursing documentation and how it may be improved. Results showed that 80% of patients (n = 56) had a stoma care chart filed in their medical

notes. However, the nursing staff had only completed one part of the entire stoma care chart. Documentation on the type of operation and stoma type was missing in 53% of the patient's medical records. This information is important in determining the appropriate stoma care. Reasons for insufficient documentation with the stoma care charts were the use of ambiguous language and the lack of form standardization. Staff also indicated that they felt that the stoma care chart was not viewed by other nurses and therefore was ineffective in improving patient care. Variability in documentation can cause difficulties in clinical care with potential miscommunication between providers.

A wide variability in documentation was illustrated in a conceptual content analysis of charts from patients who had undergone stoma surgery for gastrostomy and/or ostomy (Kapsandoy, 2014). Differences in bedside nurse charting and wound/ET nurse charting were revealed in the documentation of color, location, size, severity, skin integrity, normal skin, and healing progression (Figure 1). Nurses used multiple unique phrases to describe the color, size, and location of the peristomal skin. For example, wound/ET nurses tended to use exact measurements or approximations such as, "0.2 cm wide" while bedside nurses used relative terms such as, "small area" to describe the size of peristomal lesions. Results also showed that bedside nurses used symbols such as "@" and simple descriptors such as "around site" to describe the location of the lesions while wound/ET nurses used a "clock" reference such as "proximal area from 10 to 2 o'clock." Additionally, bedside nurses used nonstandard symbols and abbreviations such as "WNL, CDI, √/ ~~0"~~ to describe normal peristomal skin. A majority of bedside nurse charting also lacked documentation on the condition of the peristomal skin area. Minimal documentation was included on the healing progression.

Benefits of Standardized Documentation

Accurate, pertinent, and up-to-date documentation promotes effective and consistent communication between nurses and other members of a healthcare team. Lunney, Delaney, Duffy, Moorhead, and Welton (2005) argued that the use of standardized nursing language can help describe care delivered, and can provide data to explain and predict nursing care. Mann and Williams (2003) asserted that patient care can directly benefit from the standardization of nursing documentation.

Several other studies support these arguments. An initiative by O'Conner, Earl, and Hancock (2007) was intended to improve nursing documentation for acute adult patients in four hospitals, each with its own format of nursing documentation. These investigators found that the introduction of a standardized format resulted in a positive effect on documentation completion, communication, and patient care at all sites.

Mascolo (2006) found that introducing a standardized assessment and documentation of skin and wound care improved its consistency and accuracy. Muller-Staub, Needham, Odenbreit, Lavin, and van Achterberg (2007) implemented standardized terminology for nursing diagnosis (NANDA), Nursing Interventions Classifications (NIC), and Nursing Outcomes Classifications (NOC) in 12 hospital wards, and found improvements in documentation of nursing diagnosis ($p < 0.0001$), etiology-specific nursing interventions ($p < 0.0001$), and nursing-sensitive patient outcomes ($p < 0.0001$).

Thoroddsen and Ehnfors (2007) found similar improvement in the documentation of daily nursing care (assessment, $p < 0.05$; diagnosis, $p < 0.01$; and interventions, $p < 0.01$) for inpatients in a 900-bed national hospital after the implementation of

standardized languages for nursing documentation: (a) Functional Health Patterns (FHP) for nursing assessment, (b) NANDA for nursing diagnosis, and (c) NIC for nursing interventions.

The use of standardized terminology in peristomal and stoma care would have several advantages, including the ability to: (a) compare research on nursing care (nursing diagnosis, interventions, outcomes), (b) compare data across clinical populations, settings, geographical areas, and time, (c) identify trends related to patient problems and nursing care provided, and (d) improve data for quality assurance evaluation (Saba & McCormick, 2006). A need exists for standardized terminology and measurement of peristomal skin lesions to clearly assess incidence, prevalence, treatments, interventions, and patient outcomes at both local and national levels.

Using a standardized terminology provides a consistent way to measure and manage peristomal skin lesions. Different types of lesions can be monitored and interventions can be matched with peristomal skin lesions, thereby enhancing the practicability of evidence-based guidelines. The quality of nursing care provided to stoma patients can be enhanced by the use of evidence-based interventions. These interventions can be developed by conducting research related to definitions and research related to specific interventions for peristomal skin lesions.

The use of standardized assessment tools could enhance concept/clinical descriptions and reduce assessment variation between clinicians (Jemec & Wulf, 1997; Nybaek et al., 2010). Providing more meaningful and reliable nursing data may be achieved by using structured documentation and standardized languages (Dochterman et al., 2005; Keenan et al., 2003).

Electronic Health Records (EHR) and Nursing Terminologies

Electronic health records (EHR) have received national attention as a critical tool to improve healthcare quality, safety, and cost effectiveness (Zlabek, Wickus, & Mathiason, 2011). The development of standardized terminology for interoperability, practice, and documentation practices has become a high priority for various areas of care including peristomal and stomal care. In both paper-based (Bjorvell, Wredling, & Thorell-Ekstrand, 2003) and electronic patient documentation (Ammenwerth et al., 2001; Thoroddsen & Ehnfors, 2007), using standardized documentation may improve completeness of nursing documentation (Daly, Buckwalter, & Maas, 2002; Darmer et al., 2006) and continuity of care (Keenan & Yakel, 2005).

Continuous efforts are being made at both the national and international level, particularly in some disciplines such as nursing (Barthold, 2009; Nailon, 2007) and nutrition (Hakel-Smith & Lewis, 2004), to standardize terminology and semantics. Examples of nursing contributions to these efforts include, but are not limited to, (a) the development of standardized language for clinical care, such as NANDA, NIC, NOC; (b) the development of the nursing minimum data set (NMD) and nursing management minimum data set (NMMD); and (c) working with established terminologies such as SNOMED CT to ensure nursing terminology is represented (Lunney et al., 2005; Saba & McCormick, 2006).

The next step in research is to conduct studies that look at the standardization of terminology in peristomal skin lesions. Additionally, studies using standardized terminology need to be conducted at the national level. These studies should look at incidence/prevalence, interventions, and outcomes in peristomal skin lesions in both

adults and children. In recent years, several efforts have been made to develop classification systems for peristomal skin conditions. Stages of skin lesions borrowed from fields such as dermatology have been suggested (Lyon et al, 2000; Lyon & Smith, 200; Rolstad & Erwin-Toth, 2004). A common classification method used includes subdividing peristomal skin lesions by time of occurrence. These subdivisions include early complications (1-15 days after surgery) such as edema, bleeding, necrosis/ischemia, abscess, retraction, mucocutaneous junction detachment, malposition, skin lesions, and acute dermatitis, and late complications (15 days or more after surgery) including trauma, chronic dermatitis, prolapse, fistula, hernia, stenosis, folliculitis, granuloma, and hemorrhage (Lyon & Smith, 2001).

To establish definitions for proposed stomal and peristomal complications, Colwell and Beitz (2007) conducted a cross-sectional survey of 2,900 clinical experts registered in the Wound, Ostomy, and Continence Nursing (WOCN) Society database. A total of 686 participants responded to the survey with their evaluations of the proposed definition. Results demonstrated high consensus rates for definitions and interventions, with definitions scoring higher. Using a scale of one to four, the definitions and interventions mean score was 3.64 (SD = 0.30) and the overall survey's Content Validity Index (CVI) was 0.91. These efforts to establish classification systems or consensus definitions have not, to date, resulted in an assessment tool that can be used by clinicians.

Peristomal Skin Assessment Instrument

The Studio Alterazioni Cutanee Stomali (SACS™) instrument (Appendix A) was developed by a group of seven ET nurses and four surgeons in Italy to help establish a standardized language and objective method for assessing the peristomal skin (Bosio et

al., 2007). To develop the instrument, a prospective observational study was conducted in eight centers. A total of 656 patients were assigned to two groups according to how much time had elapsed since undergoing stoma surgery. Patients' peristomal skin was examined at three different time intervals (0, 12, and 24 weeks) post stoma surgery, and changes documented with both clinical observations and digital image acquisition. The study data were used to develop the classification scheme that was based on recurrent clinical manifestations (lesions) and topographical location. Five of the most commonly observed lesions (L) in the study (included in the instrument) were hyperemic, erosive, ulcerative, ulcerative fibrinous/necrotic, and proliferative. The severity of the skin lesion was assessed on a five-point scale L1, L2, L3, L4, and LX with L1 as mild skin erosion, up to L4 as severe skin erosion and LX reflecting skin tissue overgrowth (proliferative). Location of the peristomal skin lesion was documented using five topographical (T) location quadrants.

The instrument was evaluated in Italy and the United States. In Italy, four experts (two ET nurses and two surgeons) validated the classification scheme (Bosio et al. 2007). Validity of the classifications was measured using agreement among diagnoses, with results indicating a high strength of agreement, *K* value = 0.91 (Bosio et al., 2007). The instrument's content validity was validated in the United States using 166 WOC nurse experts. The instrument demonstrated good content validity with an overall mean = 3.75 and overall content validity index (CVI) = 0.94 (Beitz et al., 2010; Beitz & Ho, 2010). In addition, Beitz et al. (2010) established that the criteria used for lesion (L) description and topographical locations (T) bear a similar resemblance to those used in wound depth description and breast cancer grid for lesion location, and have universal familiarity.

Currently, the SACS™ instrument has not been tested with real-life stoma patients or by nonexperts (Beitz et al., 2010; Beitz & Ho, 2010). The instrument has not been evaluated in the pediatric population. The SACS™ instrument was designed for use by expert nurses. Prior to this study, a small pilot study was conducted with parents to modify the instrument's language to match parent reading level and comprehension, and to determine whether the survey questions and data collection process planned for this study were appropriate. Results from the pilot study were used to verify that the data collection tools used in the study were appropriate and were not included in the dissertation study results (Bosio et al. 2007).

Alternative Instrument Considered

One potential alternative instrument was identified. An Ostomy Skin Tool was developed by 12 ostomy care nurses from various countries in conjunction with an ostomy product manufacturer (Martins et al., 2010; Martins, Tavernelli, & Serrano, 2008). The tool consisted of two parts: a DET score and a diagnostic guide. The first part involved assessing the skin in three domains – discoloration (D), erosion (E), and tissue overgrowth (T). Within each domain, a score between zero and three for the area (percentage of the area under the stoma appliance adhesive barrier) affected, and a score between zero and two for the severity, was assigned. The scores from each domain were combined to create the DET score, which ranged between zero and 15.

The second part involved classification of the peristomal skin lesions according to the diagnostic guide descriptions and clinical assessment (Martins, Tavernelli, & Serrano, 2008). The tool's intra- and interrater variability was recently evaluated by Jemec et al. (2011) using 20 ostomy care nurses from Denmark and Spain. The tool demonstrated

high intrarater reliability (K = 0.84) and moderate interrater reliability (K = 0.54) with higher interrater reliability seen between the experts (K = 0.70).

Rationale for Selection of the SACS™ Instrument

The two peristomal skin assessment instruments described above are fairly new and studies evaluating their use in living patients are limited. Studies addressing stoma and peristomal skin assessment instruments, intervention, and outcomes in the pediatric population are deficient and warrant attention. The SACS™ instrument was selected for this study because its content validity was evaluated in the United States (Beitz et al., 2010) and because it was less complex to use. The reduced complexity was important because this study included parental use of the tool.

Psychometric Evaluation of Assessment Instruments

The purpose of this study was to evaluate the feasibility of use and psychometric properties of the SACS™ instrument when used by nurses and parents to describe a peristomal skin lesion in children with stomas. Psychometrics, or the scientific evaluation of assessment instruments, was introduced in Chapter 1 as the methodological framework guiding this study. This section provides additional information regarding psychometric principles and approaches. It begins with foundational material that includes a description of the two major approaches that guide design and interpretation of measurement instruments. These approaches are the norm-referenced framework and the criterion-referenced framework. Measurment error plays a centeral role in psychometrics and is discussed next. Two essential psychometrics criteria, reliability and validity, are then discussed, including procedures for evaluating instrument reliability and validity.

Measurement Frameworks

Norm-referenced framework

The norm-referenced framework is used when the focus of the measurement tool assessed individual performance in relation to the performance of a well-defined norm or comparison group. The aim of the measure is to discriminate among subjects possessing differing amounts of the measured characteristics. How well the subject performs compared to other subjects is highly relevant (Waltz et al., 2010). The measurement challenge is to identify the appropriate comparison group.

An example of a norm-referenced tool is the 60-item Stress of Discharge Assessment Tool (SDAT-2) developed by Toth (Waltz et al., 2010). SDAT-2 measures stress experienced by myocardial infarction patients during discharge and early recovery. Scores range from 60 to 300 points, where high stress is indicated by a high score and low stress by a low score. The meaning of the score for an individual subject is considered within the context of scores obtained by other subjects who respond to the same tool. Physiologic variables such as blood pressure are often evaluated as norm-referenced variables, because the “normal” values are defined by age.

Criterion-referenced framework

The criterion-referenced framework is applied when the focus of the measure is in assessing a subject’s performance in relation to a specifically defined set of characteristics (Waltz et al., 2010). A key feature of a criterion-referenced measure is categorization. The aim of the measure is to discriminate among subjects who have a targeted set of characteristics and those who do not. Unlike norm-referenced framework, how well the subject performs against other subjects is irrelevant. The measurement

challenge is to precisely define the behaviors and the cut points or categories that will discriminate between subjects who exhibit various amounts of the characteristic.

The SACS^{TM} instrument is an example of a criterion-referenced measure. The SACS^{TM} instrument is designed to classify peristomal skin lesions into categories of progressive skin deterioration (hyperemic, erosive, ulcerative, proliferative, granulation) and the location of the lesion in relation to the stoma. The instrument provides photograph guides of the lesion types along with a text description.

Measurement Error

According to classical test theory, an observed score obtained by a measurement instrument is comprised of a "true" score (unobservable) and an "error" in the measurement process (Frank-Stromborg & Olsen, 1997, Waltz, Strickland, & Lenz, 2010). The "true" score is the one that would be obtained if an instrument were perfect (Frank-Stromborg & Olsen, 1997, Waltz, Strickland, & Lenz, 2010). Achieving accurate results is the goal of all measurement although perfect accuracy is not possible since there is always some level of measurement error. Error can be introduced from the instrument or from use of the instrument in a particular manner. Sound approaches to measurement are intended to reduce the amount of error (Waltz et al., 2010). There are two categories of measurement error: random and systematic error.

Random error

Random error (chance or variable error) is unsystematic and occurs due to chance factors that affect measurement of the variable. Reliability of a measure is directly influenced by random error – the less random error that is introduced in the measurement

process, the higher the reliability and vice versa. Performing many independent measurements can cause the fluctuation of observations due to random error to cancel each other out. Sources of random error include temporal factors, imprecision in the measurement process, and imprecision in the measure (Waltz et al., 2010).

Systematic error

Systematic error (bias) occurs due to factors that consistently affect the measurement of the variable. For example, if a patient thermometer was calibrated incorrectly so that it reads 0.5^{o}C higher than the actual temperature, repeated temperature readings will always be 0.5^{o}C high. Bias is a threat to the validity of a measure – the less systematic error that is introduced in the measurement process, the higher the validity, and vice versa. Unlike random error, the sources of systematic error do not fluctuate and are usually associated with lasting characteristics of subjects, the measurement instrument, or the method and/or process (Waltz et al., 2010).

Precision and Accuracy

Precision is the degree to which repeated measurements by the same subject or across different raters are consistent, or in agreement (Waltz et al., 2010). Precision reflects the spread of measurement variability caused by random errors – a narrower distribution reflects higher precision. Precision is a prerequisite for accuracy (Waltz et al., 2010). *Accuracy* is the degree to which observed scores are correct; usually operationalized as the agreement with scores from a gold standard. The gold standard, although not a perfect measure, is considered to be the best method to measure a defined variable (Waltz et al., 2010).

Reliability

Reliability Assessment

Reliability (repeatability or consistency) is the degree to which an instrument or measurement procedure produces the same results when measurements are repeated under the same conditions (Carmines & Zeller, 1979; Waltz et al., 2010). Reliability estimates typically range between zero and one. The closer the estimate to one, the more reliable the instrument (Frank-Stromborg & Olsen, 1997; Nunnally & Bernstein, 1994; Waltz et al., 2010).

Three facets of reliability may be examined: stability, equivalence, and internal consistency. When a characteristic is relatively unchanged over time, *stability* can be assessed. A characteristic is assessed at two or more time points and the correspondence of those ratings is calculated. For stability assessments, the timing between ratings is crucial. The interval between ratings should be long enough so that raters do not recall the previous response to the items, which may cause false inflation of the reliability estimate. However, the interval time should not be so long that the characteristic changes. In that case, the study becomes about stability of the characteristics rather than the performance of the instrument (Frank-Stromborg & Olsen, 1997; Kimberlin & Winterstein, 2008).

When an instrument is used by multiple people, *equivalence* assessments examine the consistency with which scores are assigned by the raters, this assessment examines the extent to which the observers can be considered as interchangeable. When an instrument can exist in two or more forms or versions, equivalence assessments examine the extent to which the versions can be considered as alternative instruments and thus can

be used interchangeably. To be considered as equivalent tests, two criterion-measures should have (a) the same set of test specifications used in their construction and (b) items relatively homogeous in nature. Two norm-referenced measures should have (a) the same procedures and objectives used in their construction (same test specifications), (b) approximately equal means, (c) equal standard deviation and, (d) equal correlations with any third variable (Waltz et al., 2010).

Reliability assessments of *internal consistency* examine the relationship between items within the instrument. When an instrument contains multiple items to measure the same attribute, the scores on those items should correspond (Waltz et al., 2010).

Reliability Procedures

All reliability procedures can be applicable to both criterion-referenced and norm-referenced measures. The consistency with which categories are assigned is a primary focus for criterion-referenced measures. These measures are most often evaluated using intrarater reliability, interrater reliability, test-retest, and parallel forms procedures. Norm-referenced measures are typically assessed using test-retest, parallel forms, or internal consistency procedures (Waltz et al., 2010).

When items on a measure are subjective, the criteria to assign scores are subject to interpretation by each rater. Two types of reliability assessments are important for subjective measures. *Intrarater reliability* refers to the consistency with which a single rater assigns scores on two occasions. This can be a reflection of the stability of subjective observations. *Interrater reliability* refers to the consistency across different raters that assign scores to the same object or observation. Two or more trained raters simultaneously observe an event and rate the event independently, using established

rating criteria. The agreement across the different raters is then examined (Frank-Stromborg & Olsen, 1997; Kimberlin & Winterstein, 2008; Waltz et al., 2010).

Test-retest procedures assess the stability of a score from a group of raters. The same test or assessment is given at two different time points (time one and time two, for example). The scores for time one and time two assessments are then correlated using appropriate statistical procedures

Parallel forms procedures assess the consistency of two equivalent (alternate) tests that measure the same domain, using items that represent the same concept(s). The reliability estimate is based on the scores of the same subject taking test A and test B. When the tests are taken on a single occasion, form equivalence is assessed. If the tests are taken at different occasions, both form equivalence and stability are assessed. The correspondence between the two sets of scores are statistically calculated (Waltz et al., 2010).

A reliability procedure that is often applied for instruments that contain multiple items is known as *internal consistency*. Internal consistency assessment is used to assess the degree to which a set of items within an instrument measure the same concept. The instrument is used by a set of subjects or observers that represent the population of interest, and responses are statistically examined to determine the extent to which the responses to different items within the instrument correspond.

Statistical tests for reliability procedures

The specific statistical tests employed in a reliability evaluation depend on the nature of the scores obtained by the instrument. Interval level data with wide variability are typical of norm-referenced measures, for example, and these data are often amenable

to parametric tests. Criterion-referenced measures often yield ordinal or categorical data with limited range, and thus nonparametric statistics may be more appropriate. However, when scores for criterion-referenced measures are reported as a percentage, parametric statistics may still be appropriate (Waltz et al., 2010). Figure 3 summarizes reliability procedures and related statistics for criterion-referenced and norm-referenced measures. Statistical tests for reliability assessments using intrarater, interrater, test-retest, and parallel forms procedures are similar. Reliability, by definition, examines the agreement, correspondence, or correlation between instrument scores or ratings. An appropriate correlation statistic is used to assess the degree of agreement between the scores. Scores are typically assessed using the Pearson product-moment correlation coefficient (Pearson r) for interval level data, Spearman's rho for ordinal level data (or interval data that are not normally distributed), and Chi square is used for ordinal or nominal data. However, these statistics have a limitation in that they essentially evaluate relative correspondence – the set of scores {1,2,3} and the set of scores {8,9,10} will yield high correlation statistics. Percent agreement reflects absolute scores and can be a more stringent index of the correlation between scores. For intrarater and interrater reliability, a commonly-used alternative to percent agreement is the *kappa* statistic (Cohen's kappa), which adjusts for chance agreement. When there are two or more raters, a weighted kappa or equivalent statistical procedure such as the Fleiss kappa or intraclass correlation (ICC) can be used (Waltz et al., 2010).

Statistical methods to assess internal consistency include the split-half technique (items in the instrument are split into two halves and scored separately) and Cronbach coefficient alpha, which represents the mean of all possible split-half coefficient for the

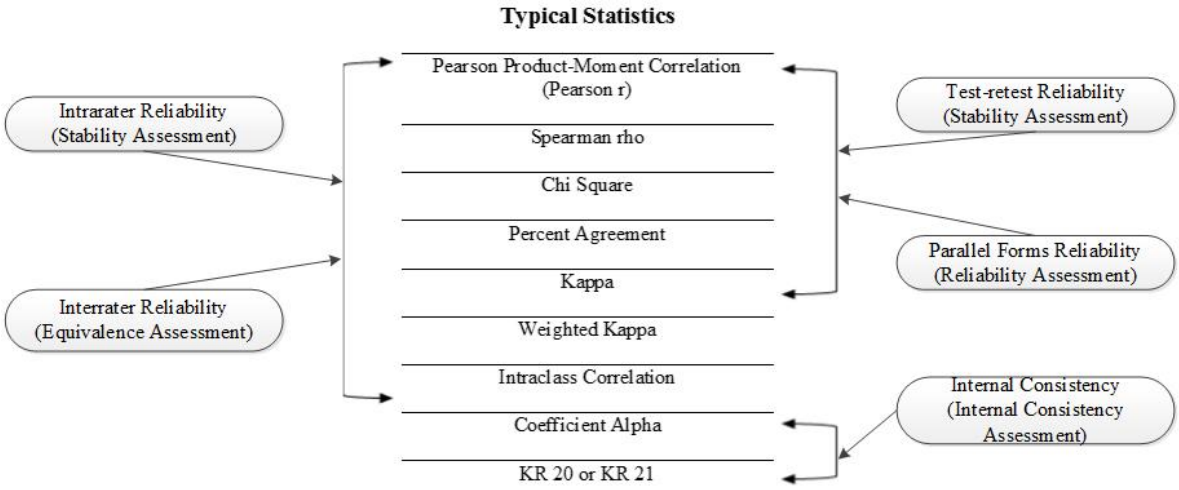


Figure 3. Reliability procedures and statistics

set of data. Kuder-Richardson Formula (KR 20 and KR 21) are sometimes used as statistical alternatives to Cronbach alpha (Frank-Stromborg & Olsen, 1997; Kimberlin & Winterstein, 2008; Waltz et al., 2010).

SACS™ Instrument Reliability Assessment

The SACS™ instrument is a criterion-referenced measure. The items on the instrument are relatively subjective. There are only a limited number of categories on the instrument but the appearance of peristomal skin can vary widely and is not likely to exactly match the pictures and descriptions. Observers must interpret the descriptions and determine which category best matches their observations. Therefore, interrater and intrarater reliability were assessed. Peristomal skin can change rapidly so photos of the peristomal skin were used to ensure the area being assessed did not change between assessments. Test-retest, parallel forms, and internal consistency procedures were not applicable to the SACS™ instrument and were not assessed in this study.

Validity

Validity Assessment

Validity evaluates the extent to which evidence and theory support the interpretation of the measurements for the intended use, that is, whether an instrument measures what it purports to measure (Frank-Stromborg & Olsen, 1997; Waltz et al., 2010). Validity evidence is built over time with repeated use of the measure. Validity should be assessed every time an instrument is used in a different context or for a different purpose. Different aspects of validity should be investigated depending on the purpose of the instrument and context of use (Waltz et al., 2010).

Validity is considered a unitary concept that has historically been organized into categories: face, content, criterion-related, and construct validity (Waltz et al., 2010). Face validity examines how well the instrument appears, on superficial examination, to measure the proposed construct. Face validity provides no evidence of what the instrument really measures and is therefore considered a very weak form of validity (Frank-Stromborg & Olsen, 1997; Waltz et al., 2010).

Content validity assesses how well the instrument adequately samples all the items that could be used to measure the construct. It evaluates the extent to which the entire domain of the construct is measured (scope) and the extent to which all facets of the domain are represented (Frank-Stromborg & Olsen, 1997; Waltz et al., 2010).

There are two subcategories of criterion-related validity, predictive and concurrent. Both assess the correlation between an instrument measure and another measure (criterion) that is considered to measure the same underlying construct. The measures of the instrument are then correlated to the criterion measures. For predictive

validity, data for the criterion variable are collected from the same subject at a later date rather than at the same time of the instrument use. For concurrent validity, data for the criterion variable are collected at the same time as the instrument measure (Frank-Stromborg & Olsen, 1997; Waltz et al., 2010). Criterion-related validity assessments can be applicable for norm-referenced and criterion-referenced measures (Waltz et al., 2010).

Construct validity assesses the degree to which the instrument reflects the construct it purports to measure. All evidence of validity ultimately contributes to construct validity evidence, although some procedures are specifically intended to reflect construct validity (Frank-Stromborg & Olsen, 1997; Waltz et al., 2010).

Types of Validity Assessment Evidence

Five sources of evidence can be considered when examining instrument validity. These are test content, response processes, internal structure, relationship to other variables, and the consequences of testing. These sources of evidence may explain difference aspects of validity (Waltz et al., 2010).

Evidence based on *test content* examines the fit between the content domain and conceptual framework, and the items on an instrument (including item content and the format of those items). Evidence based on test content typically reflects content validity and/or construct validity. Examples of assessment procedures include expert review, item analysis (e.g., to examine definitions compared to the conceptual framework), and assessment of evidence that subgroups of subjects may have unfair advantage or disadvantage due to selection of items or how they are represented (Waltz et al., 2010).

Evidence based on *response process* examines the fit between the construct and the type of responses elicited by the instrument. This can assess potential sources of bias,

such as social desirability, that systematically influence responses. Examples of assessment procedures include interviewing subjects about why they responded in a certain manner, observing subjects as they engage in tasks related to the instrument, or examining the way observers apply criteria and definitions to rate an observation (Waltz et al., 2010).

Evidence based on *internal structure* examines the extent to which individual items match the operational definition of the construct. Statistical procedures such as factor analysis can evaluate the extent to which item responses suggest that the items measure the same attribute. Differential item function studies (another statistical technique) evaluate item bias that can examine interrelationships between items (Waltz et al., 2010).

Evidence based on the *relationship to other variables* examines how well the instrument items correspond to similar measures, as well as how well the instrument items differ from measures that evaluate a different construct. Criterion-related validity assessments, by definition, use evidence based on the relationship to other variables. Differential group prediction studies, meta-analyses and other evaluations of generalizabilty, and multitrait-multimethod approaches also commonly use evidence based on the relationship to other variables (Waltz et al., 2010).

Evidence based on *consequences of testing* examines the extent to which anticipated outcomes are realized (positive consequence), or the extent to which negative consequences occur. Consequences may be examined to see if they differ in various subgroups of participants. Typical procedures include focus groups and descriptive studies (Waltz et al., 2010).

Validity assessment procedures

Any validity assessment procedure might be applicable to an instrument, depending on the purpose and context of use, regardless of whether the instrument is a norm-referenced measure or criterion-referenced measure. Validity may be assessed at the overall test or item level (or both). The concern for a criterion-referenced measure includes only whether the measure assesses what it purports to measure but also whether it functions in accordance with its intended purpose. Thus, decision validity is especially important for a criterion-referenced measure. Decisions about cut scores used to classify observations directly impact validity assessments (Waltz et al., 2010).

Face validity assessments typically consist of a (fairly superficial) examination of the instrument to determine if it appears to measure the intended construct. The instrument may be examined by experts, laypersons, or people who represent the intended study participants. The extent to which items are understandable even by naïve users may be evaluated (Waltz et al., 2010).

Content validity focuses on the degree to which the items on the instrument adequately represent the content domain. Content valdity is mainly a function of how the instrument was developed so literature can be a source of evidence for content validity. The hallmark of content validity assessment is the review by two or more content experts who examine the definition of terms, the list of objectives that guided the measure construction, and the list of items. The experts may qualitatively assess the items. For formal quantitative assessments, the experts may link the items to objectives with the agreement on this linkage evaluated statistically (item-objective evaluation). Delphi studies or similar techniques can be used to examine relevance, clarity, and sufficiency of

the items. Statistical procedures that examine agreement between the content experts include a calculation of simple percent agreement or average percent agreement, measures of interrater agreement such as kappa statistics, calculation of a content validity index (CVI), or calculations such as the alpha coefficient (Waltz et al., 2010).

Criterion-related validity assessments examine how well the instrument performs, compared to another instrument or measure (the criterion), which comes from an established, preferably well-validated instrument. For concurrent validity, the instrument variable and criterion variable are measured at the same time. Predictive validity assesses correlation to a criterion measure that is obtained at a later time than the instrument measure. Statistical procedures may examine the correlation between the measures or the effect of different subgroups on prediction or correlation. Meta-analysis can be considered a criterion-related validity assessment that examines evidence across studies, and evaluates generalizability to other settings (Waltz et al., 2010).

Construct validity represents the accumulation of evidence from all types of assessments. Criterion-referenced measures, contrasted groups, hypothesis testing, and decision validity assessments are commonly used approaches. For norm-referenced measures, typical approaches include contrasted groups, hypothesis testing, factor analysis, and multitrait-multimethod analyses. However, any of the approaches could be used for either norm- or criterion-referenced measures when circumstances warrant (Waltz et al., 2010). Major approaches to evaluating construct validity are described here, but other approaches may also be used to evaluate construct validity.

Decision validity is an especially relevant approach for criterion-referenced measures. It examines the level of confidence with which subjects can be classified.

Assessment of decision validity requires a comparison to a “correct” response (gold standard). The level to which subjects are correctly classified is evaluated. Statistics may include the percent of observations that are classified correctly. Sensitivity and specificity analyses can be appropriate assessments of decision validity when decisions can be fittingly classified as true or false positive and true or false negative (Waltz et al., 2010).

For a *contrasted groups* approach to construct validity, groups of subjects are identified that are known to be low or high on the attribute being measured. The instrument scores are assessed to determine if the groups differ in mean instrument ratings/scores and if the scores differ in the expected direction. For example, subjects that are known to have less pain might be expected to have a lower mean score on a pain scale than the subjects who are known to have extensive pain. Ratings from observers who are expected to differ in some relevant characteristic might be compared (Waltz et al., 2010).

Hypothesis testing approaches are somewhat similar to contrasted groups but the comparisons are driven by theory (expected group differences). This includes experimental studies where an intervention group is expected to have different scores than a control group, observational studies that examine theorized correlations between variables, or studies that examine specific participant subgroups.

For the contrasted groups approach and the hypothesis testing approach, statistical tests to assess group differences are used. These include ANOVA, independent *t*-tests, Chi square, or similar evaluations as appropriate for the level of data recorded by the instrument.

Factor analysis is appropriate for measures in which conceptual attributes are measured by multiple items. Scores on items that are expected to measure the same

attribute are expected to be statistically correlated. The correspondence between the underlying conceptual framework and the item correlations should be congruent (Waltz et al., 2010).

Multitrait-multimethod studies may provide strong validity evidence but are limited to situations when two or more constructs are being measured using two or more methods/instruments, the constructs and instruments are assumed to be independent, and all assessments can be administered to all subjects. *Convergent validity* suggests that items that measure the same construct should have high correlation. *Divergent validity* suggests that items that measure different constructs should have low correlation.

SACS™ instrument validity assessment

The Studio Alterazioni Cutanee Stomali (SACS™) instrument (Appendix A) was developed in Italy to help establish a standardized language and objective method for assessing the peristomal skin (Bosio et al., 2007). Some psychometric assessments have been reported.

Face validity. In the process of developing an ostomy algorithm, Beitz et al. (2010) evaluated preliminary face validity of the SACS™ instrument using nine WOC nurse experts. Face validity was not reported in other literature.

Content validity. Content validity for the SACS™ instrument has been reported in the literature. The SACS™ instrument was developed by a group of clinical stoma experts consisting of seven ET nurses and four surgeons in Italy (Bosio et al., 2007). The experts conducted a prospective observational study in eight national ostomy centers between 2003 and 2006. Patients were assigned to two groups according to how much time had elapsed since undergoing stoma surgery. The peristomal skin of 656 patients

(380 in group 1 and 276 in group 2) were examined at intervals of 0, 12, and 24 weeks and changes documented over time using clinical observations and digital image acquisition. Peristomal skin lesions were found in 339 (52%) patients (272 men; 67 women). These patients were then included in the subsequent study to develop the skin lesions definitions and classification scheme currently reflected in the SACS™ instrument. The classification scheme was based on recurrent clinical manifestations (lesions) and topographical location as revealed in their study data.

Bosio et al. (2007) subsequently validated the classification scheme using four experts (two ET nurses and two surgeons). The experts were asked to classify 20 peristomal skin lesion images using a draft of the classification scheme with an accompanying multiple choice questionnaire. Agreement among diagnosis and strength of the agreement were used to measure the validity of classification with results indicating a high strength of agreement ($K = 0.91$) (Bosio et al., 2007).

In 2009, the instrument's content validity was validated in the United States using 166 WOC nurse experts (Beitz et al., 2010). The WOC nurse experts were asked to rate the relevance/importance of each item and format to the content domain on a scale of one to four where one = Not relevant/Not important and four = Very relevant/very important. The instrument demonstrated good content validity with an overall mean of 3.75 and overall content validity index (CVI) of 0.94 (Beitz et al., 2010).

Criterion-related validity. Criterion-related validity requires that the instrument be compared to another established (well-validated) measure (Waltz et al., 2010). Currently, there are no established measures for peristomal skin assessment. As of today, no studies have assessed the SACS™ instrument's criterion-related validity.

Construct validity. Construct validity examines the extent to which a test measures the intended construct; it is often reflected in the appropriateness of inferences or decisions made on the basis of observations or measurements (Waltz et al., 2010). No studies to date have reported the SACS™ instrument's construct validity.

Summary of the Literature

The clinical context for this study was surgical stomas and peristomal skin lesions. A paucity of peristomal skin lesion research in the pediatric population currently exists. A majority of studies regarding peristomal skin lesions have been conducted with adult patients and, even when included in studies, pediatric patients were only a small percentage of the sample. Evidence of differences between adult and children's skin varied, but, in general, suggested that young children may have more vulnerability to skin lesions than adults. Given the lack of pediatric evidence regarding peristomal skin lesions, and inconclusive evidence regarding differences in skin physiology parameters, the development of high-quality evidence regarding peristomal skin lesions in the pediatric population has become a significant need.

Examining peristomal skin lesion evidence across studies has been problematic due to a lack of consensus in definitions and terminology, and differences in study design, populations, and measurement timing. Nursing documentation of peristomal skin has also been highly variable with little consensus regarding what, how, and where to document such observations. A method to consistently measure and document peristomal skin lesions is clearly needed. Such a method would support research and evidence-based practice, and would support communication. However, there is no widely accepted peristomal skin lesion classification tool. Two potential peristomal skin assessment

instruments have recently been developed. The SACS™ instrument was selected for potential use in the study site (PCH) because of reduced complexity, prior validity evidence, and because previous evaluation included U.S. populations.

Measurement instruments should be evaluated prior to use in any new context. Therefore, this study was designed to evaluate the feasibility of parents and nurses using the SACS™ instrument in the pediatric setting. In particular, the aim was to evaluate psychometric properties of the instrument when used in that context. Instrument evaluations (psychometrics) involve a variety of types of evidence that are accrued over time. Fundamental psychometrics concepts were summarized in the literature review, including methods and procedures commonly used for psychometric evaluations, which supported the methods used in this study.

CHAPTER 3

METHODS

Research Approach

The purpose of this prospective observational study was to evaluate the SACS™ instrument feasibility and psychometric properties. Feasibility of instrument use was assessed with a questionnaire (Appendix B). Prospective observational data evaluated psychometric properties (inter- and intrarater reliability, construct and decision validity) related to the SACS™ instrument's severity and location ratings. The study aims were to determine:

1. The extent to which it is feasible for parents and nurses to use the SACS™ instrument to rate a child's peristomal skin.
2. The evidence of reliability when the SACS™ instrument is used by parents and nurses to describe a child's peristomal skin lesion.
3. The evidence of validity when the SACS™ instrument is used by parents and nurses to describe a child's peristomal skin lesion.

Setting and Study Population

The study took place in Salt Lake City, Utah during May 2012 to May 2013. Although the Salt Lake population is predominantly Caucasian (75%), there is a mixture of other racial/ethnic groups and nearly 1/4 of the population (22.3%) is Hispanic or

Latino (U.S. Census, 2010). Salt Lake City is the largest city in the Intermountain West and one of only two major urban areas in the Great Basin. Primary Children's Hospital (PCH) is a 289-bed facility that serves the needs of children in five states: Utah, Idaho, Wyoming, Nevada, and Montana. The hospital is recognized as one of the top children's hospitals in the United States and is equipped to treat children with complex illnesses and injuries, including stoma surgery. In the year 2012, the Wound Care and Ostomy Department nurses provided enterostomal services to 2830 stoma patients. In 2013, the number of patients increased to 4014.

Participants were purposively selected from PCH. Children with stomas and peristomal lesions were identified by bedside nurses, who then notified the wound/ET team. The wound/ET nurses notified the principal investigator (PI). The PI checked to see if the bedside nurse, parent, WOC nurse expert, and wound/ET nurse were all available at the same time. If so, the PI approached the parent to explain the study purpose and obtain informed consent. All sequential patients for whom the study participants met inclusion criteria and logistics (all participants available at the same time) were included in the study. All participants had to be able to speak, read, and write the English language. Inclusion criteria for the various participants were:

1. Parents of children ages 1 month (full-term and preterm infants) to 18 years who had undergone stoma surgery for ostomy and/or gastrostomy purposes and were the primary caretaker. The time required for preterm infant skin to postnatally adapt is said to be dependent on gestational age, with more premature infants requiring longer time to mature (Afsar, 2010). Preterm infants greater than 4 weeks postnatally were included in the child population of interest because there

is evidence that for many preterm infants, by 2 to 3 weeks post partum, the epidermal layer of a preterm infant is similar to that of a full-term infant (Cartlidge, 2000; Nikolovski et al., 2008).

2. The WOC nurse expert (gold standard) had to be certified as a wound, ostomy, and continence nurse expert and have had experience working with pediatric stoma patients.
3. The Wound/ET nurses had to work with the wound/ET team providing care for pediatric stoma patients and not be certified as WOC nurse expert.
4. Bedside nurses must have been an RN working on a patient unit at PCH, not certified as a WOC nurse expert, not a member of the wound/ET nursing team, and whose duties included caring for patients with stomas.

Sample Size

Because the study was descriptive, classical power analysis to determine sample size did not apply. Pragmatic consideration determined the sample size for the WOC nurse expert and the Wound/ET nurses. There was only 1 WOC nurse expert at PCH. The wound/ET department at PCH consisted of 9 wound/ET nurses all of whom were invited to participate. The number of bedside nurses was primarily determined by the sample size of children, number of bedside nurses employed at PCH, and the likelihood of the same nurse caring for multiple stoma patients.

Peristomal skin lesion observations were viewed as independent events because the condition of peristomal skin can change in as little as 24 hours. An analysis of sample size needed to determine intraclass correlation suggested that a sample of 20-25 lesions would be sufficient, with four raters, alpha = .05 and beta=.2, roughly analogous to 80%

power (Bonett, 2002). The estimated number of observations for this study was based on the following considerations: (a) The pediatric surgery department at PCH performs approximately 10-15 stoma surgeries a month, (b) the Wound/ET department performs approximately 200 stoma related patient consults per month, and (c) there must be at least a 1-week time lap between measurements of two different peristomal skin lesion on the same patient. It was also recognized that not all patients who had peristomal skin lesions would also have all four types of study participants available at the same time. These considerations suggested it was reasonable to obtain at least 50 observations for this exploratory study.

Ethical Considerations

The study was approved by the University of Utah IRB and Primary Children's Hospital. Prior to bedside data collection, written consent and demographic information was obtained from the WOC nurse expert and wound/ET nurses. Written consent was obtained from parents and bedside nurses at the child's bedside prior to instrument training and data collection. Verbal assent was obtained from all children. Written child assent was obtained from children ages 7 to 17 who were capable of providing assent. Written assent was not obtained from children with any medical condition such as developmental delay, which affected their ability to give written assent. Parent or guardian permission for photographing the child’s stoma and peristomal skin was also obtained.

Confidentiality of data was maintained at all times, and participants were not identifiable in the research data set. The research data were kept on a secure server hosted

at the College of Nursing, accessible only to the investigator and committee chair. Laptops and portable devices that were used to collect patient, clinician, and parents' instrument ratings and questionnaire responses were encrypted and password secured. Device encryption was verified by the hospital's information system security office.

Procedures

SACS™ Instrument Training

All participants received standardized training from the PI on how to use the SACS™ instrument prior to rating the child's peristomal skin. Standardized training consisted of SACS™ instrument handout (Appendix A) augmented with verbal instructions and a demonstration on how to use the instrument. Verbal instructions to parents included modified language to match parents' reading and comprehension level. Successful completion of the standard training was demonstrated when the participant correctly rated a sample picture of a peristomal skin lesion using the SACS™ instrument at the end of the training.

Data Collection Procedures

The WOC nurse expert and wound/ET nurse demographic information were obtained prior to going to the bedside, at the time they consented to participate in the study. At the bedside, parents and bedside nurses who consented to participate received the standardized SACS™ instrument training. Parents completed a brief questionnaire with demographic items and feasibility questions about parents' willingness to use the SACS™ instrument at home, technology access, and communication preferences (Appendix C). Bedside nurse demographic data were obtained at the bedside.

The participants were instructed not to consult one another or share their ratings prior to the direct observation (Figure 4). The child's peristomal skin was then exposed and all 4 participants were asked to individually rate the peristomal skin using the SACS^{TM} instrument at the same time on individual data sheets (Appendix B). After rating the peristomal skin, the participants responded to questions on the individual data sheet regarding the ease or difficulty of using the SACS^{TM} instrument. The individual data sheets were then collected from the participants by the PI. The PI then took photographs of the child's peristomal skin using digital and cell phone cameras (Figure 4 and Appendix D) according to the standards described by Rennert, Golinko, Kaplan, Flattau, and Brem (2009) on wound photography.

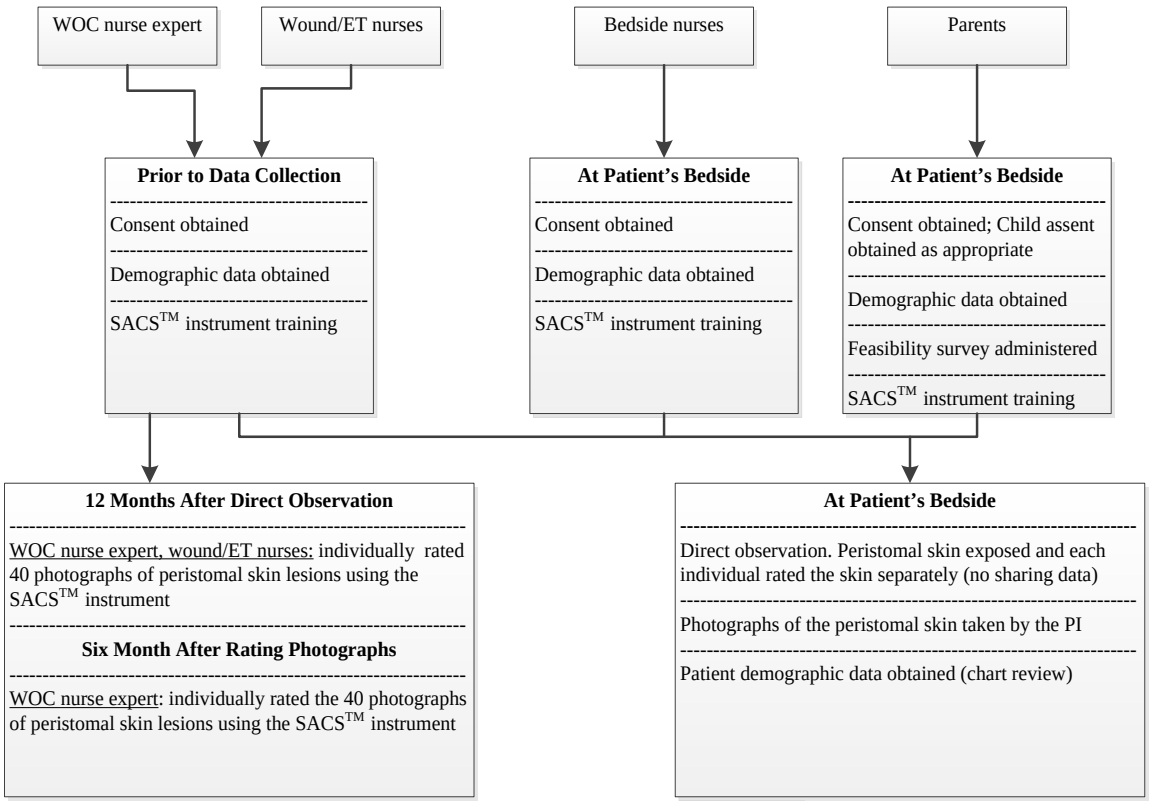


Figure 4. Research procedures (flow).

Procedure for Rating Photographs

After 12 months of bedside data collection, 40 photographs of peristomal skin lesions were selected to represent all levels of lesion severity. This "lag time" was intended to prevent photograph ratings from being biased by a recall of the direct observation of the lesion. The photographs were de-identified and loaded into an iPad for standardized photography resolution. The WOC nurse expert and wound/ET nurses individually rated the 40 photographs from the iPad using the SACS^{TM} instrument. Six months after rating the 40 photographs, the WOC nurse expert rated them a second time.

Photography Protocol

A high-resolution Digital Single-Lens Reflex (D-SLR) camera was used because it allowed for immediate review of the image, easy storage or delete based on the image quality, and the upload of images into a secure database. In addition, the view seen by the user was representative of the image that was stored (Rennert et al., 2009). Wound photography techniques described by Rennert et al. (2009) were used. To minimize error, the following guidelines were adhered to by the PI when photographing the stoma and peristomal skin.

1. Expose the peristomal skin by removing all dressings, stoma pouch, and skin barrier.
2. Cleanse the peristomal skin using normal saline.
3. Write the patient ID and date on a disposable ruler.
4. Write the words “head” on one end of a disposable ruler and “feet” on the opposite end.
5. Place the disposable ruler on the healthy skin next to the stoma (do not place over

affected skin) with “head” pointing towards the patient’s head and “feet” toward the patient’s feet.

6. Photograph the entire peristomal skin to include the stoma, healthy skin, surrounding cellulites, and disposable ruler.
7. Upload image into secure database with pertinent information (patient study ID, location, type of stoma).

Data Analysis Plan

The data were analyzed using the Statistical Package for Social Sciences (SPSS, version 17) and Microsoft Excel software. The demographic characteristics of the children, parents, and nurses were analyzed using descriptive statistics (e.g., counts and percentages). Feasibility (Aim 1) was assessed with a questionnaire. Descriptive statistics were used to summarize quantitative items from the questionnaire. Participant comments were grouped into themes.

Peristomal skin lesions on children who had undergone stoma surgery were assessed and given SACS^{TM} instrument ratings by four types of observers: a WOC nurse expert, a wound/ET nurse, a bedside nurse, and the child’s parent. Those ratings formed the basis for psychometric evaluations of reliability and validity. The SACS^{TM} instrument categorizes (rates) lesions by type (assigning L codes) and topographical location (assigning T codes). Erosive lesions (L1-L4 rating, termed *severity* for this study) was considered separately from granulation tissue (LX rating). The SACS^{TM} instrument severity (L) ratings are in order of increasing severity.

A clinically important threshold was identified by consensus among the WOC nurse expert and the wound/ET nurses. Wound care clinicians would need to examine L3

and L4 lesions before recommending treatment. Less severe lesions could be managed by the parent at home without needing to come to clinic first. Therefore, for some assessments, the severity ratings were collapsed into dichotomous categories around this decision threshold - whether a parent would be advised to bring a child to the clinic (L3, L4) or could treat the lesion at home without coming to the clinic (No lesion, L1, L2).

Reliability

Reliability (Aim 2) was assessed with intrarater and interrater reliability procedures. Intrarater reliability refers to the consistency with which a rater assigns scores on multiple occasions. Interrater reliability refers to the consistency across different raters that assign scores to the same object or observation. The agreement across the ratings is then examined (Frank-Stromborg & Olsen, 1997; Kimberlin & Winterstein, 2008; Waltz et al., 2010).

Intrarater reliability

The WOC nurse expert evaluated lesions on three separate occasions. The expert initially rated peristomal skin based on direct observation at the bedside. Pictures taken at the same time as the direct observation were rated after 12 months of bedside data collection. The same pictures were rated a second time after a time lag of 6 months. The SACS™ instrument ratings by the expert were used to assess intrarater reliability. The analysis included picture to picture and picture to direct comparisons.

Interrater reliability

The entire wound team, including the WOC nurse expert, rated pictures of peristomal skin using the SACS™ instrument. For each observation, the L1-L4 (erosive

lesions) and LX (granulation tissue) were compared. In addition, L1-L4 severity ratings were collapsed into two categories and examined around the decision threshold (L3 or L4 versus no lesion, L1, or L2).

Reliability statistics and interpretation plan

For intrarater reliability, the percent agreement (Po) and Cohen's Kappa (κ) statistics were calculated. Percent agreement had useful clinical meaning because it reflects error frequency and measurement precision (Waltz et al., 2010). Cohen's Kappa adjusts for chance agreement. For interrater reliability, the percent agreement (Po) and intraclass correlation (ICC) statistics were calculated. ICC is equivalent to Cohen's Kappa that has been weighted for multiple raters (Waltz et al., 2010).

Percent agreement was interpreted as follows: 0-4% as no agreement, 4-15% as minimal, 15-35% as weak, 35-63% as moderate, 64-81% as strong, and 82-100% as almost perfect agreement (McHugh, 2012). Kappa values were interpreted as follows: values ≤ 0 as no agreement, 0.01–0.20 as slight, 0.21–0.40 as fair, 0.41– 0.60 as moderate, 0.61–0.80 as substantial, and 0.81–1.00 as almost perfect agreement (McHugh, 2012; Viera & Garrett, 2005). ICC values were interpreted as follows: <0.40 was poor, 0.4 to 0.75 was fair to good, and >0.75 was excellent (Fleiss, 1986). According to Waltz et al. (2010), guidelines for acceptable values are percent agreement values greater than or equal to 0.80 or Kappa greater than or equal to 0.25.

Validity

In this study, face validity was informally assessed in the selection of the instrument and in a small pilot study conducted as preliminary work for this study. No

formal analysis was applied. Some of the participant comments were found, after content analysis, to be relevant to the scope and completeness of the instrument and thus were categorized as content validity evidence.

Construct validity

Construct validity was a focus for Aim 3. The contrasted groups approach to construct validity evaluates whether subsets of the data, when compared, vary in a direction that corresponds with the domain of knowledge underpinning the instrument. Groups of subjects are identified that are known to be low or high on the attribute being measured and the instrument ratings compared. Differences in mean instrument ratings, when the lesions actually differed in severity, support construct validity. Alternatively, ratings from observers who are expected to differ in some relevant characteristic might be compared. The instrument scores are assessed to determine if the groups differ in mean instrument ratings/scores and if the scores differ in the expected direction (Waltz et al., 2010).

Contrasted groups approach: Severity of the peristomal lesion

The contrasted groups approach to construct validity examined whether the mean instrument ratings appropriately varied for different severity peristomal skin lesions (the actual characteristic being assessed). Lesions were categorized as low severity (no lesion or L1), medium severity (L2), or high severity (L3 or L4). Observations where there was "No lesion" were grouped with L1 lesions because there were a low number of those observations. L4 lesions were grouped with L3 lesions because of the low number of L4 lesions. The lesion severity ratings by the wound/ET nurse and the wound expert were

averaged. Then the average was grouped as low, medium, or high by rounding to the nearest whole number. This was considered to represent the actual lesion severity. The ratings by the parents and bedside nurses were averaged and considered to represent the scores produced by the instrument (instrument rating). A one way ANOVA was conducted to determine whether the instrument could distinguish between lesions of known severity. The dependent variable was the average instrument rating. The independent variable was the actual lesion severity and had 3 levels (low, medium, high).

Contrasted groups approach: Known groups of observers

Parents and bedside nurses have less experience with stomas than members of the wound team (Wound/ET nurses and the WOC nurse expert) and so it was expected that ratings would differ between these known groups of participant types, particularly for the more subjective assessments. The contrasted groups approach to construct validity, based on known groups, was assessed for lesion severity (L1-L4) ratings, for the presence of granulation tissue (LX) ratings, and for lesion location. These assessments require different amounts of clinical knowledge. Severity ratings require the most interpretation and the most clinical knowledge. Location requires the least amount of interpretation and clinical knowledge. Lower correspondence for ratings that require more interpretation, than the correspondence for ratings that require less interpretation, supports construct validity because it reflects the hypothesized differences in the observers. To determine the extent to which severity (L1-L4) ratings from parents and bedside nurses correspond to ratings from the wound team, a Spearman rho correlation and kappa were computed for the severity (L1-L4) ratings and for the presence of granulation tissue (LX). Locations could be any combination of the possible location ratings (e.g., T1 + T5).

Therefore, to simplify analyses, the location rating from all other observer types was compared to the WOC nurse expert and categorized as an exact match, overlap (partial match), or no match. A Chi-square test was calculated to assess if the distribution of match, partial match, or no match was significantly different between the three non-expert roles (parents, bedside nurses, and wound/ET nurses).

Decision validity approach

One of the primary anticipated purposes for use of the SACS^{TM} instrument in the pediatric setting was to make a clinical decision regarding whether or not the child would need to come to clinic for assessment of a peristomal skin lesion after discharge. Higher levels of confidence for decisions supports construct validity for criterion-referenced measures (Waltz et al., 2010). Therefore, the decision validity around the predetermined clinical indicators driving this decision was examined as key evidence of construct validity. The decision was a binary classification test to determine whether the peristomal skin lesion, had it occurred in the outpatient setting, would have been severe enough to be seen in clinic. The decision that would have been made based on the WOC nurse expert rating was considered to represent the correct decision.

The decision about whether a child with a new peristomal skin lesion needs to be seen in clinic depends on two characteristics: granulation tissue or LX rating, and lesion severity. The presence of granulation tissue requires that the child's stoma area be evaluated by a clinician, regardless of the severity of any erosive lesion. Lesions with L3 or L4 severity must be seen in clinic to determine a management plan. Lesions with L2 severity or lower can be treated at home without the child having to be brought to the clinic.

Decision validity: Presence of granulation tissue

Granulation tissue is assessed as present or absent. The LX ratings for direct observations (parents, bedside nurses, wound/ET nurses) and pictures (wound/ET nurses) were compared against the direct observation ratings of the WOC nurse expert. Percent agreement was calculated to determine the degree of agreement between the WOC nurse expert LX lesion severity ratings and LX lesion severity ratings by other participants. Additionally, a phi coefficient statistic was calculated to determine the degree of association between the expert's LX lesion ratings and the LX lesion ratings by other participants. The phi coefficient is a specialized variation of the correlation coefficient, used when the two states of a variable can be represented as zero and one. It is commonly used to examine dichotomous attributes like living/dead, accept/reject, or present/absent (Chedzoy, 2006).

Decision validity: Lesion severity

Categorization based on the threshold was essentially a binary classification test using a clinically important threshold (Freeman & Moisen, 2008). The decision can be thought of as a test of whether or not the child needs to come to the clinic. L1 and L2 lesions can be treated by the parent at home (negative test result) and L3 and L4 lesions need to be seen in clinic (positive test result). The ratings by the WOC nurse expert were considered to represent truth (correct response). These assumptions allowed computation of sensitivity (the proportion of observations where the lesion was correctly identified as needing to be seen in clinic, sometimes called true positive rate) and specificity (the ability to exclude a condition, the proportion of observations where the lesion was correctly identified as able to be treated at home, sometimes called true negative rate).

Using the assumption that the WOC nurse expert represents the correct response, and the nonexpert represents the test, the following definitions were used to calculate sensitivity and specificity:

- True positive: Both raters indicated L3 or L4
- False positive: Nonexpert rated as L3 or L4, wound expert rated as L1 or L2
- True negative: Both raters indicated no lesion, L1, or L2
- False negative: Nonexpert rated as no lesion, L1 or L2; wound expert rated lesion as L3 or L4

CHAPTER 4

RESULTS

This study examined the SACS™ instrument as a tool for describing peristomal skin lesions in children who had undergone stoma surgery. Feasibility evaluation (Aim 1) included ease of use and pragmatic factors related to electronic communication between parents and nurses. Psychometric evaluation included reliability (Aim 2) and validity (Aim 3) assessments.

Sample Description

The characteristics of the children in whom peristomal skin lesions were observed are presented in Table 1. There were 65 children, mainly Caucasians (*n* = 59) with slightly more females (*n* = 36, 55%) than males. The mean age was 74.3 months (slightly older than 6 years). Age groups included infants (4 weeks to 1 year), children (1 to 12 years), and adolescents (13 to 18 years). There were a total of 73 peristomal skin lesion events.

Parent demographic characteristics are presented in Table 2. There were 65 parents, mainly Caucasians (*n* = 57, 92%) with more females (*n* = 58, 91%) than males. A majority of parents were between the ages of 20 and 39 (*n* = 49, 75%). 89% of parents had achieved at least a high school diploma or GED, 44% had completed at least some postsecondary education. Another 29% had completed high school education.

Table 1
Patient (Child) Demographic Characteristics

Demographic Characteristic	*N*	Distribution	%
Gender	65		
Male		29	45%
Female		36	55%
Age Stage (months)	65		
Term neonatal (Birth to <27 d)		1	2%
Infancy (28 d to 12 m)		16	25%
Toddler (13 m to 23 m)		6	9%
Early childhood (24 m to 71 m)		13	20%
Middle childhood (72 m to 143 m)		14	22%
Adolescence (144 m to 227 m)		15	23%
Ethnicity	65		
Hispanic, Latino, or Spanish Origin		7	11%
Not Hispanic or Latino		58	89%
Race	63		
Asian		1	2%
Native Hawaiian or other Pacific Islander		2	3%
White or Caucasian		59	94%
Mixed (more than one race)		1	2%
Type of Stoma	65		
Gastrostomy		51	79%
Ostomy		10	15%
Gastrostomy and Ostomy (both)		4	6%

Table 2
Parent Demographic Characteristics

Demographic Characteristic	*N*	Distribution	%
Gender	64		
Male		6	9%
Female		58	91%
Age	64		
Less than 20 years		2	3%
20 – 24 years		13	20%
25 – 29 years		10	16%
30 – 34 years		15	23%
35 – 39 years		11	17%
40 – 44 years		5	8%
45 – 49 years		5	8%
50 – 54 years		2	3%
60 years and greater		1	2%
Ethnicity	64		
Hispanic, Latino, or Spanish Origin		10	16%
Not Hispanic or Latino		54	84%
Race	62		
Asian		1	2%
Native Hawaiian or Pacific Islander		2	3%
White or Caucasian		57	92%
Mixed		2	3%
Education	64		
Attended high school		7	11%
High school Diploma/GED		29	45%
Associate Degree		11	17%
Bachelor's Degree		11	17%
Graduate Degree		1	2%
Other		5	8%

Bedside nurse characteristics are presented in Table 3. There were 64 nurses, mainly Caucasian (*n* = 60, 94%) females (*n* = 56, 88%). Most had a bachelor's degree (*n* = 36, 56%). Nursing experience varied from less than 6 months to more than 11 years. Nearly one-third of nurses had over 10 years of experience. This is similar to the characteristics of the overall population of nurses at Primary Children's Hospital, although precise numbers for the nurse population were not available for comparison.

Table 3
Bedside Nurses Demographic Characteristics

Demographic Characteristic	*N*	Distribution	%
Gender	64		
Male		8	13%
Female		56	88%
Age	64		
Less than 24 years		5	8%
25 to 29 years		16	25%
30 to 34 years		13	20%
35 to 39 years		6	9%
40 to 44 years		9	14%
45 to 49 years		5	8%
50 to 54 years		7	11%
54 years and greater		3	5%
Ethnicity	64		
Hispanic, Latino, or Spanish Origin		2	3%
Not Hispanic or Latino		62	97%
Race	64		
Asian		3	5%
Native Hawaiian or other Pacific Islander		1	2%
White or Caucasian		60	94%
Education	64		
Associate Degree		23	36%
Bachelor's Degree		36	56%
Graduate Degree		5	8%
Nursing Experience	62		
Less than 6 months		6	8%
6 months to 1 year		4	7%
1 to 2 years		4	7%
3 to 4 years		14	23%
5 to 6 years		8	13%
7 to 8 years		3	5%
9 to 10 years		5	8%
11 years and greater		18	29%

Table 4
Wound Nurse Demographic Characteristics

Demographic Characteristic	*N*	Distribution	%
Role	10		
Wound Expert		1	10%
Wound Nurse		9	90%
Gender	10		
Male		1	10%
Female		9	90%
Age	10		
25 – 29 years		1	10%
30 – 34 years		3	30%
35 – 39 years		2	20%
50 – 54 years		1	10%
54 – 59 years		3	30%
Ethnicity	10	10	
Not Hispanic or Latino			100%
Race	10		
White or Caucasian		10	100%
Education	10		
Associate Degree		5	50%
Bachelor's Degree		4	40%
Graduate Degree		1	10%
Nursing Experience	10		
3 to 4 years		2	20%
5 to 6 years		1	10%
9 to 10 years		1	10%
11 years and greater		6	60%

Wound nurse characteristics are presented in Table 4. All were Caucasians and most (*n* = 9) were females. Half had an associate degree (*n* = 5). A majority (*n* = 6) had 11 years nursing experience or more. These 10 nurses were the entire wound/enterostomal therapy team at the organization at the time of the study.

Feasibility of Using the SACS™ Instrument

Ease of Use

Participants were asked to rate the overall ease of use of the SACS™ instrument (Table 5). The questionnaire was given with each lesion rating, so 6 parents, 9 bedside nurses, and 8 wound nurses responded at least twice. All responses indicated that the instrument was easy or very easy to use. Participants were asked if they found any part of the SACS™ instrument difficult to use or understand. The instrument was rated as not difficult to use or understand in more than 80% of the responses.

Participants were also asked to comment on anything they found difficult to use or understand with the SACS™ instrument. Difficulties expressed by the participants are presented in Table 6. Rating the location of the lesion was the most common difficulty expressed by the study participants.

Feasibility of Parent Use at Home

Pragmatic issues regarding potential use of the SACS™ instrument after the parent brings the child home from the hospital were explored. The questionnaire items assessed the parent's technology access, communication preferences while at home, and willingness to use the SACS™ instrument at home.

Technology access issues included access to the Internet and access to equipment

Table 5
SACS™ Instrument Ease of Use

	WOC Nurse Expert (*n*=72)	Parent (*n*=71)	Bedside Nurse (*n*=73)	Wound Nurse (*n*=73)
Ease of Use (%)				
Very Easy	82%	45%	34%	41%
Easy	11%	49%	48%	56%
Hard	1%	0%	1%	0%
Neither easy or hard	6%	6%	16%	0%
Difficulty with Components (%)				
No difficulty	88%	90%	86%	92%
Had difficulty	13%	10%	14%	8%

Table 6
Difficulties Experienced with Using the SACS™ Instrument

Participant Comments
Location
• Difficulty assessing lesion location especially when patient was agitated
• Difficulty determining the lesion location especially with g-tubes because they obstruct the complete view of the peristomal skin
Severity
• Difficulty distinguishing lesion severity with small lesions
• Difficulty determining lesion severity with multiple lesions
• Difficulty distinguishing lesion severity when patient had topical treatments such as silver nitrate that may alter the skin lesion color
Granulation tissue
• Difficulty determining granulation tissue

to send photos of skin lesions. However, the majority of parents (90%) indicated that they had Internet access at home. Further, most parents owned digital (85%) and cell phone (97%) cameras of which 91% were able to use their digital camera and 97% could use their cell phone camera to send photographs using text or email.

Most parents were willing to use email or text (73%), text message only (14%), or email only (10%) to communicate with a wound/stoma care nurse. Additionally, many parents were willing to send photographs of their child's peristomal skin lesion to a wound/stoma care nurse using email or text messaging (67%), text messaging only (22%), and email only (8%).

An overwhelming number of parents (98%) were willing to use the SACS™ instrument to rate their child's peristomal skin lesion and use the instrument to communicate with a wound/stoma care nurse while at home. A majority of parents also indicated that they thought the instrument would be very easy (43%) or easy (48%) to use at home. No parent felt that the instrument would be hard or very hard to use at home. Communication preferences and parent access are shown in Table 7.

SACS™ Instrument Reliability

Intrarater Reliability

Intrarater reliability assessment examined multiple ratings of the same event by the same rater. The WOC nurse expert rated all peristomal skin lesions using the SACS™ instrument during the bedside observation (direct observation). The expert rated 40 peristomal skin lesion pictures on two separate occasions. The two sets of picture ratings were compared (picture to picture) and direct observation ratings were compared to the first picture ratings (picture to direct). The percent agreement and kappa for severity

Table 7
Parent Communication Preferences and Access

Question	N	n	%
Technology Access			
Do you have Internet access at home?	62		
No		6	10
Yes		56	90
Do own a digital camera?	62		
No		9	15
Yes		53	85
Able to text or email photographs with digital camera	53		
No		5	9
Yes		48	91
Do you own a cell phone that has a camera?	63		
No		2	3
Yes		61	97
Able to text or email photographs with cell phone camera	59		
No		2	3
Yes		57	97
Communication Preferences			
Would you be willing to communicate with a wound/stoma care nurse using email or text messaging, if asked to do so?	63		
Yes, Email only		6	10
Yes, Text Messaging only		9	14
Yes, Email or text messaging		46	73
No, Not willing to communicate using email or text messaging		2	3
Would you be willing to send pictures to a wound/stoma care nurse using email or text messaging, if asked to do so?	63		
Yes, Email only		5	8
Yes, Text Messaging only		14	22
Yes, Email or text messaging		42	67
No, Not willing to communicate using email or text messaging		2	3
Willingness to use Instrument			
After your child goes home and you needed to talk with the wound/stoma nurse about your child's stoma. Would you be willing to rate your child's stoma using the SACS™ instrument while at home?	63		
No, Not willing to SACS™ instrument at home		1	2
Yes, Willing to use SACS™ instrument at home		62	98
How hard do you think it would be to rate your child's stoma at home using the SACS™ instrument?	61		
Very easy		26	43
Easy		29	48
Neither easy or hard		6	10

ratings suggested weak agreement for the picture to picture comparison (P_o = 50%; κ = 0.357, $p < 0.001$) and fair agreement for picture to direct comparison (P_o = 50%; κ = 0.369, $p < 0.001$).

The presence of granulation tissue (LX) ratings is a clinically important determination. Granulation tissue percent agreement for the intrarater reliability assessment was strong, with moderate kappa for picture to picture (P_o = 80%; κ = 0.529, $p = 0.001$) comparisons and for picture to direct (P_o = 83%; κ = 0.581, $p < 0.001$) comparisons.

McHugh (2012) suggested that a lower percent agreement is very common for subjective measures (such as lesion severity), and that meaningful categorization may be a more important consideration. Therefore, intrarater reliability was assessed with the severity ratings grouped by a predetermined, clinically important threshold (no lesion, L1, or L2; versus L3 or L4). This threshold differentiates lesions that need to be seen in clinic (L3 or L4) from lesions that do not need to be seen in clinic. When observations were dichotomized by this threshold, the percent agreement was strong with a substantial kappa for picture to picture (P_o = 85; κ = 0.671, p <0.001) and the percent agreement was strong with moderate kappa for picture to direct (P_o = 78; κ = 0.529, $p = 0.001$) comparison (Table 8).

Interrater Reliability

Interrater reliability assessment involves multiple raters evaluating the same event. All the wound/ET nurses and WOC nurse expert each rated the same 40 pictures of peristomal skin lesions. The ratings for severity (L1-L4) and granulation tissue (LX) were used to assess interrater reliability. Results are presented in Table 9. There was moderate

Table 8
Intrarater Reliability (Dichotomous Categories)

	Severity Rating		Granulation (LX)	
	Picture-Picture	Picture-Direct	Picture-Picture	Picture-Direct
% Agreement (P_o)	85%	78%	80%	83%
Interpretation	Strong	Moderate	Strong	Strong
Kappa (κ)	0.671 ($p < 0.001$)	0.456 ($p = 0.003$)	0.529 ($p = 0.001$)	0.581 ($p < 0.001$)
Interpretation	Substantial	Moderate	Moderate	Moderate

Table 9
Interrater Reliability

	Picture Severity Rating (L1 – L4)	Picture Severity Rating Dichotomous Reliability	Picture Granulation (LX) Rating
% Agreement (P_o)	62%	87%	91%
P_o Interpretation	Moderate	Almost perfect agreement	Almost perfect agreement
Intraclass	Average Measures	Average Measures	Average Measures
Correlation (ICC)	0.914 ($p < 0.001$) 95% CI 0.867 - 0.949	0.914 ($p < 0.001$) 95% CI 0.866 - 0.949	0.946 ($p < 0.001$) 95% CI 0.916 - 0.968
ICC Interpretations	Excellent	Excellent	Excellent

CI = confidence interval

percent agreement and excellent intraclass correlation for severity (Po = 62%; ICC = 0.914 with a 95% confidence interval from 0.867 - 0.949, p < 0.001). As in the intrarater reliability assessment, binary severity categorization was also used (No lesion, L1, or L2; versus L3 or L4). The percent agreement increased to almost perfect and ICC remained excellent for the picture severity rating comparisons with binary categorization (Po = 87%; ICC = 0.914 with a 95% confidence interval from .866 - .949, p < 0.001).

Granulation (LX) ratings also demonstrated high percent agreement and ICC (Po = 91%; ICC = 0.946 with a 95% confidence interval from 0.916 - 0.968, $p < 0.001$).

SACS™ Instrument Validity

Face Validity

Face validity was informally evaluated by the 9 wound nurses and the WOC nurse expert. All 10 nurses agreed that the instrument seemed to measure peristomal skin lesions. The instrument was examined by 3 parents and 3 bedside nurses, who agreed that the pictures and text definitions appeared understandable. The parents and bedside nurses voiced interest in using the tool, stating they felt it would help them to communicate about the child's stoma.

Content Validity

Some WOC nurse expert, wound nurse, and bedside nurse comments were relevant to the SACS^{TM} instrument content (Table 10). In particular, limitations were identified, including lack of detail, inability to account for all skin problems, and picture limitations. These limitations were consistent with findings of previous literature reporting instrument content validity.

Construct Validity

Contrasted Group Approach

Using the contrasted groups approach to construct validity, this study included a comparison of instrument ratings to the actual severity of the peristomal lesion (the characteristic being assessed) as operationalized by the WOC nurse expert rating of the lesion severity. The contrasted groups approach to construct validity was also used to

Table 10
Participant Comments Relevant to Content Validity

Participant Comments
Other skin problems
• Instrument did not account for other peristomal skin problems for example, “Vesicles, unopened”
• Instrument did not account for other peristomal skin problems [example: “Had flap of skin from 6-11 o'clock, not granulation tissue”]
• Instrument did not account for other peristomal skin problems such as yeast infections
Missing detail
• Instrument did not distinguish between scar tissue and hypergranulation
• Inability to describe the degree of severity within a category, for example “very mild erythema approximately 0.2 cm” using the instrument
• Difficulty distinguishing lesion severity for some lesions [examples: “Wound appeared in between L2 and L3”; “For different patients normal pink versus L1 redness”; “I wasn't sure if I should include the red inner rim of the stoma”]
Picture issues
• Pictures did not exactly match the patient lesions [example: “The part that is hard is that the photos are very clear but what the patient's wound actually looked like was very different for me”

examine differences in ratings between known groups of observers.

Contrasted groups approach: Lesion severity

Lesion severity was categorized as low severity (No lesion or L1), medium severity (L2) or high severity (L3 or L4). A one way ANOVA was conducted to determine whether the instrument could distinguish between lesions of known severity. Know lesion severity was determined based on the direct observation severity ratings by the WOC nurse expert. There was a significant difference in instrument scores for low, medium, and high severity lesions ($F=21.98$, $p<.001$). The mean instrument rating for low severity lesions was the lowest (average rating 1.2). The mean instrument rating for medium severity lesions was in the middle (average rating 1.5) and the mean instrument

rating for high severity lesions was the highest (average rating 2.5). The ability to distinguish between lesions of known severity and the average ratings being in the expected order (increasing average rating for low, medium, and high severity ratings) supports construct validity.

Contrasted groups approach: Known groups of observers

The wound team (including the WOC nurse expert and wound/ET nurse) is expected to have more experience with peristomal skin lesions than bedside nurses or parents. It was hypothesized that the observer's level of experience with peristomal lesions might influence ratings, and that there would be least correspondence for the more subjective items on the SACS™ instrument. Lesion severity and granulation tissue ratings require clinical judgment. The severity rating is the most subjective item. There are a small number of discrete categories whereas the actual appearance of skin can be highly variable and complex. Granulation tissue is rated as present or absent.

For each lesion, the average rating by the wound team was compared to the average rating by the bedside nurse and parent. A Spearman rho correlation was computed to examine the correlation between ratings and a kappa statistic was computed (Table 11). There was a significant positive correlation (0.597, $p < .001$), indicating that the two sets of ratings tend to move in the same direction (generally correspond). However, the relatively lower kappa statistics suggest that the two groups differ in their ratings.

The location rating is the least subjective rating on the SACS™ instrument. Location rating simply requires the determination of the stoma's vertical and horizontal

Table 11
Contrasted Groups – Severity and Granulation Tissue

Rating	Spearman rho	Interpretation	Kappa	interpretation
Severity (L1-L4)	.597 (p<.001)	moderate	.270	fair
Granulation (LX)	.597 (p<.001)	moderate	.419	moderate

midline to identify a location quadrant. SACS™ instrument location ratings can be a single quadrant (e.g., T1) or a combination of quadrants (e.g., T1 and T2).

Because of the large number of potential combinations, location ratings by the other observers were compared to the WOC nurse expert location rating for each lesion and categorized as an exact match, an overlap (partial match), or no match. Wound/ET nurses' location ratings corresponded exactly or overlapped with the WOC nurse expert rating for 87% of observations (Table 12).

Correspondence between the WOC nurse expert and parents was 85% while correspondence between the WOC nurse expert and bedside nurses was 81%. There were nearly as many "overlap" as "exact match" observations for each type of rater. The distribution of match, partial match, no match was not different between the three non-expert roles (χ^2= 1.602, p = .808).

Overall, the pattern of the known groups corresponded to the expected group differences, with more correspondence for less subjective values. Thus the findings from the contrasted groups evaluation support construct validity.

Construct validity – Decision validity approach

The parents provide ostomy care after hospital discharge. When a parent calls the wound team about a peristomal skin lesion, the decision about whether the lesion can be treated at home, or if the child needs to be seen in clinic, hinges primarily

Table 12
Contrasted Groups – Location

Group compared to WOC expert	Exact Match	Overlap/Partial Match	Total Match
Parents	44%	41%	85%
Bedside nurses	44%	37%	81%
Wound/ET nurses	49%	38%	87%

on two aspects: the presence or absence of granulation tissue, and the severity of the skin lesion. Thus, the decision validity approach to construct validity was important for the SACS™ instrument. This approach evaluates the decision that would have been made based on instrument ratings.

Decision validity: Presence of granulation tissue

The presence of granulation tissue means the child must come to the clinic, regardless of other assessments of lesion severity. The WOC nurse expert LX ratings, based on direct observation at the bedside, were the gold standard. The bedside ratings by the wound/ET nurse, bedside nurse, and parent were compared to the gold standard response (Table 13). The wound team picture LX ratings were also compared to the gold standard rating, under the premise that the wound team members would be the clinicians to whom parents might email a picture of the stoma.

Percent agreement and the Phi coefficient (φ) were computed for the binary decision (come to the clinic or treat at home) based on the presence or absence of granulation tissue. Wound nurses had the highest percent agreement (89% for direct observation and 85% for pictures) with the gold standard, followed bedside nurses (82%), and parents (81%). All of phi coefficients were statistically significant. There was a moderate positive association between the WOC expert nurse and parents ($\varphi=0.567$, $p <$

Table 13
Decision Validity: Granulation Tissue

Rater compared to WOC nurse expert direct observation rating	Percent Agreement with Expert	Phi (φ)
Parents	79%	0.533 ($p < 0.001$)
Bedside nurses	82%	0.592 ($p < 0.001$)
Wound/ET nurses	89%	0.753 ($p < 0.001$)
Picture rating	85%	0.592 ($p < 0.001$)

.001) and between the WOC nurse expert and bedside nurses (φ=0.592, $p < .001$). The WOC expert nurse and wound nurses had a strong positive association (φ=0.753, $p <$ .001). Overall, the high percent agreement and moderate to strong positive associations indicate that the WOC nurse expert and nonexperts tend to agree on whether granulation tissue is present.

Decision validity: Lesion severity

Lesions with severity of L3 or L4 must be seen in clinic, whereas less severe lesions can be treated at home. The decision that would have been made, based on the WOC nurse expert rating from direct observation, was considered the gold standard, representing the "correct" decision. We compared the decision that would have been made based on parent ratings, bedside nurse ratings, and wound/ET nurse ratings to the gold standard. Results are presented in Table 14. Sensitivity and specificity were computed to examine the ratings and determine the level of confidence for decisions made using the instrument. Sensitivity reflects the true positive rate, which is how often the rater would have made a correct decision to have the child seen in clinic. Specificity reflects the true negative rate, which is how often the rater would have made a correct

Table 14
Decision Validity - Lesion Severity

Rater	True Positive	False Positive	True Negative	False Negative	Sensi-tivity	Speci-ficity
Parents	8 (11%)	4 (5%)	54 (74%)	7 (10%)	53%	93%
Bedside Nurses	8 (11%)	7 (10%)	51 (70%)	7 (10%)	53%	88%
Wound/ ET Nurses	11 (15%)	2 (3%)	56 (77%)	0%	100%	97%
Picture	49 (15%)	46 (14%)	216 (68%)	8 (3%)	86%	82%

decision that the child did not need to come to the clinic.

Decisions for wound/ET nurses showed high sensitivity and specificity, both for decisions made from direct observation and those based on pictures. Moderate to high sensitivity and specificity suggest a high confidence level about decisions by wound/ET nurses to advise a parent to bring the child to clinic or to treat the skin lesion at home.

Ratings by bedside nurses and parents showed moderate sensitivity and high specificity. High specificity reflects the true negative rate, which agrees with the decision to treat the child at home. Decisions that would have been made by parents or bedside nurses to treat the child at home have high confidence. There was less agreement for decisions that would have been made, to bring the child to the clinic (the “positive” decision, reflected in the sensitivity). Consistently, when parents or bedside nurse raters disagreed with the expert, they rated the lesion as more severe than the expert rating. This resulted in lower sensitivity evaluation, but when raters made an incorrect decision, they erred on the side of safety (bring the child in for evaluation).

CHAPTER 5

DISCUSSION AND CONCLUSIONS

Study Summary

The SACS™ instrument has been proposed as a way to document peristomal skin lesions in children with stomas. This study evaluated the SACS™ instrument for potential use by parents and nurses with various levels of stoma expertise. The study was guided by the Donabedian Structure-Process-Outcome framework in conjunction with *psychometrics* as the methodological framework. Psychometric evaluation does not occur in isolation, but rather is the accrual of evidence over time as the instrument is used in various contexts. This study examined the feasibility of use and instrument reliability and validity when used in the pediatric context. For this study, the observation and measurement of peristomal skin lesions using the SACS™ instrument occurred based on direct observation of the lesion or based on photographs of peristomal skin lesions.

SACS™ Instrument Feasibility

Most (over 80%) of the parents, bedside nurses, and wound nurses indicated that the SACS™ instrument was easy to use. Wound/ET nurses and bedside nurses used the instrument without difficulty. Several bedside nurses expressed interest in using the SACS™ instrument for documentation. For example, one nurse stated, “I like this tool! It will be good to have a standardized way to document g-tube findings.”

Parents used the SACS™ instrument without difficulty. An overwhelming number of parents (98%) stated that they were willing to use the SACS™ instrument to communicate with clinicians concerning their child's peristomal skin condition after discharge. The majority of parents (91%) indicated that the instrument would be easy or very easy to use at home. Statements included: "This is what I need at home to avoid trips to the clinic every time I call in with a question…" and "I think having this tool would make it easier to talk to a doctor or nurse about how it looks."

Parents appeared to be in favor of the idea of using technology to communicate with clinicians. More than 90% of parents were willing to use email and/or text to send photographs of their child's peristomal skin to wound care clinicians. Parents had access to appropriate technology to accomplish this communication. More than 90% of parents had access to the Internet, digital cameras, and cell phones, and stated that they knew how to use these devices to send photographs via email or text.

There are potential barriers to using technology to communicate about a child's peristomal skin. The use of cell phones and digital cameras to send photographs to clinicians will require information technology platforms that maintain privacy and security while still preserving a high-quality photographic image. Development of solutions that protect the integrity of private data during transmission can be challenging and therefore can impact the feasibility of using photographs to enhance communication.

SACS™ Instrument Reliability

Reliability reflects the consistency with which the assessment instrument measures a construct, whether across time, individuals, or situations. Reliability is necessary, but not sufficient, for validity (Waltz et al., 2010). Intrarater reliability was

examined in this study (same observer, at different times and in different situations, i.e., ratings based on direct observation versus ratings based on pictures). Interrater reliability was also assessed, comparing ratings across the 9 wound team members.

Intrarater reliability

The WOC nurse expert rated all lesions based on direct observation and, on two occasions, rated 40 lesions based on pictures. Intrarater reliability metrics for lesion severity (L1-L4) showed weak percent agreement and kappa for the picture-picture comparison and fair agreement for the picture-direct comparison. Agreement about the presence or absence of granulation tissue was strong with moderate kappa for both the picture-picture comparisons and picture-direct comparisons. The intrarater reliability metrics improved when ratings were grouped into two clinically relevant categories. Agreement was moderate for picture-picture comparisons and strong for picture-direct comparisons.

Interrater reliability

The SACS™ instrument was being evaluated for possible widespread use. Thus, it was important to evaluate ratings by multiple observers (interrater reliability). For the interrater reliability assessment, pictures of peristomal skin lesions were rated by the entire wound team, including the WOC nurse expert and wound/ET nurses. The use of pictures ensured that all raters were evaluating exactly the same peristomal skin lesion.

The SACS™ instrument interrater reliability assessments ranged from moderate to almost perfect agreement. The instrument demonstrated moderate agreement (62% agreement across 9 raters) for individual severity (L1-L4) ratings. As with the intrarater

reliability assessment, percent agreement increased to “near perfect” with binary categorization of severity ratings with 87% agreement across the 9 raters (ICC = 0.914). Agreement regarding the presence or absence of granulation tissue was also “near perfect,” with 91% agreement (ICC = 0.946).

Reliability discussion

Results provide evidence supporting reliability when the SACS^{TM} instrument is used in the pediatric setting. A certain amount of measurement variability is inevitable. Different people, or the same person at different times or in different situations, may experience phenomena differently or interpret their experience in different ways (McHugh, 2012; Waltz et al., 2010).

The amount of subjectivity, or interpretation, needed to assign a measurement category influences reliability metrics (McHugh, 2012; Waltz et al., 2010). Variables in which there are few categories, and for which the observations are sharply distinct (like survived/did not survive), are likely to achieve high reliability (McHugh, 2012). McHugh (2012) cites pressure ulcers and other skin lesions as an example of a highly subjective patient condition. Color, edema, and other details of the skin assessment are perceived differently by observers and may appear in vastly diverse ways on different patients. Reliability becomes more challenging when instruments require the rater to make fine discriminations of subjective variables, such as the amount of redness and skin erosion [as occurs with the SACS^{TM} instrument] (McHugh, 2012). Thus, the somewhat lower reliability results for individual severity ratings were not entirely unexpected.

McHugh (2012) suggested that meaningful categorization may be a more important consideration, particularly for subjective measures. When measurements were

categorized into dichotomous groups, based on a clinically relevant threshold, both intrarater and interrater reliability metrics increased substantially.

SACS™ Instrument Validity

Validity reflects the extent to which the instrument measures what it is purports to measure. Validity is particularly crucial when assessing intangible factors such as intelligence or depression, but is also important for assessments such as observations about peristomal skin. Validity is a unitary construct but it is traditionally examined in various categories (Waltz et al., 2010).

Face validity

Although face validity is considered a very weak form of validity assessment (Waltz et al., 2010), responses from the wound team nurses, bedside nurses, and parents suggested that the SACS™ instrument appeared to measure the construct (peristomal skin lesions). Contributing to the face validity is that the instrument provides photograph examples along with a text description (Appendix A).

Content validity

Content validity primarily reflects instrument development. It examines the extent to which the instrument encompasses the scope of a domain or if all relevant facets of the given construct are evaluated (Waltz et al., 2010). The SACS™ instrument had been evaluated previously for content validity, showing high content validity (CVI = 0.94) in a U.S. population (Beitz et al., 2010). Although the skin in children may be more vulnerable to breakdown, the skin assessment process is the same for children and adults (Mansen & Gabiola, 2014). Consequently, the content validity assessment was felt to be

applicable in the pediatric setting. Therefore, content validity was not a major focus of this study.

However, comments provided by the study participants highlighted some of the instrument's limitations. Participants noted that the instrument did not account for all peristomal skin problems, such as vesicles, and did not provide the ability to describe multiple lesions or add detail within a category. Additionally, the sample pictures on the instrument did not account for darker skin tones.

Construct validity

Construct validity assesses the extent to which the instrument reflects the construct that it purports to measure. All validity evidence is ultimately a reflection of construct validity, although some procedures are specifically designed to reflect construct validity (Waltz et al., 2010). For this study, the *contrasted groups approach* and the *decision validity approach* were used as methods to evaluate construct validity.

Contrasted groups approach

The contrasted groups approach to evaluating construct validity is based on the premise that, if the instrument is measuring what it purports to measure, then measurements using the instrument should vary in a way that corresponds with the construct's underpinnings. For a typical evaluation using the contrasted groups approach, *subjects* (patients) with known amounts of a characteristic are grouped to see if average ratings for the group vary as expected (Waltz et al., 2010).

Known characteristic. The SACS™ instrument purports to measure lesion severity as an important aspect of peristomal skin lesions. The instrument ratings are in

order of severity. For this evaluation, the WOC nurse expert's rating was considered to be the known, or actual, lesion severity. When the peristomal lesions were grouped as low severity (No lesion or L1), medium severity (L2), or high severity (L3 or L4) lesions, there was a significant difference in mean instrument scores (F=21.98, p <.001). The average rating increased in magnitude from low severity lesions, to medium severity lesions, to high severity lesions. Results indicate that the instrument was able to discern between lesions of known severity, providing evidence to support construct validity.

Known groups of observers. A second method for the contrasted groups approach is based on known groups of *observers* (Waltz et al., 2010). Reliability assessments had illuminated the subjective nature of the instrument. We hypothesized that the wound team (WOC nurse expert and wound/ET nurses) ratings would differ from those of the bedside nurses and parents because the wound team has more experience with skin lesions. We also hypothesized that agreement between those groups would vary according to the extent to which the item was subjective. We found lower correspondence for attributes that require clinical interpretation (L1-L4 ratings), slightly higher correspondence for granulation tissue (LX rating), and very good correspondence for location, which does not require clinical interpretation. Almost all of the "no match" or "overlap" in location ratings could be explained by a slight rotation of the instrument. Sometimes the difference was explained when either the nurse expert or the nonexpert participant did not indicate a location.

Contrasted groups summary. Overall, the contrasted groups approach provided evidence demonstrating support for construct validity. The groups varied in the expected direction, both when examining known lesions, and with known groups of observers.

Decision Validity Approach

After hospital discharge, parents are often the primary providers of ostomy care for children. Parents often call the wound care team seeking advice regarding management of their child's peristomal skin condition. It is important to determine if the child's skin problem needs to be directly assessed in the clinic or if the wound team can recommend treatment/intervention while the child is still at home. The decision depends on the severity of the lesion and the presence/absence of granulation tissue. Treatment of peristomal lesions rated L1 and L2 can often begin at home without first being examined in the clinic. Alternatively, peristomal skin lesions rated L3 or L4, or lesions with granulation tissue (LX), regardless of the severity of erosive lesions, require clinical examination. The decision validity approach to construct validity examines the extent to which there is evidence the instrument correctly supports this decision.

Granulation tissue. Results provided evidence in support of decision validity for identifying granulation tissue. Overall, there was high percent agreement (79% - 89%) and moderate to strong positive associations, indicating that the WOC nurse expert and nonexperts tend to agree on whether granulation tissue is present.

Lesion severity. Based on the predetermined, clinically significant threshold for L1-L4 lesion severity ratings, the instrument demonstrated a high sensitivity (100%) and specificity (97%) when used by wound/ET nurses based on direct observation of the lesion. This suggests high confidence in the decision and provides strong evidence for decision validity. Ratings based on pictures also demonstrated high sensitivity and specificity when the instrument was used by the wound team nurses (sensitivity 86%, specificity 82%).

Parent and bedside nurse decisions showed slightly lower sensitivity but continued to show high specificity. High specificity (true positive rate) indicates that, when these observers thought the child should come to clinic, that decision was usually correct. Lower sensitivity (true negative rate) suggests less confidence in the decision to treat the child at home, when the decision is made by a parent or bedside nurse acting on their own.

Construct validity discussion

Evidence supporting construct validity was buttressed by the contrasted groups approach based on lesions of known severity. Evidence supporting construct validity was also supported by the contrasted groups approach based on known groups of observers.

Perhaps most important clinically, there was strong evidence supporting decision validity. The instrument may help inform the decision about whether to bring the child to clinic. When the raters disagreed with the expert, they erred on the side of safety. They said the child should come in to clinic (when the expert said it was not necessary). Novice observers sometimes rate observations more severely than experts (Waltz et al., 2010). Further, experts tend to depend on the system one cognition process which produces fast, intuitive reactions, and instantaneous decisions. Therefore, they may read into situations based on their previous experience with similar lesions rather than relying strictly on what is observed (Gladwell, 2005). Thus, it was not entirely unexpected for bedside nurses and parents to rate lesions more severely than the expert ratings.

Parent ratings of lesion severity corresponded with nurse expert ratings about as well as those made by bedside nurses. Given the similarities between parent and bedside nurse findings, it is plausible to think that these participants shared similar levels of

understanding about how to use the instrument. That shared understanding, in turn, suggests that the standardized assessment provided by the instrument could support communication between parents and nurses.

Currently, the parent is always advised to bring the child to clinic and a majority of the time, the problem is found to be one that could have been managed at home without the clinician first examining the peristomal skin. Therefore, there is still an opportunity to save parents an unnecessary trip to the clinic. Communication between clinicians, and between parents and clinicians, may be enhanced by the use of photographs in addition to SACS™ instrument ratings. It appears that augmenting telephone consultations with photographs would be a safe practice that enhances the decision-making process of whether a child could be treated at home or brought to the clinic. It is feasible for most parents to send a picture of the lesion to wound team members whose assessments of these pictures have high confidence of being correct.

Study Strengths and Limitations

Strengths of the study include using rigorous data collection techniques, including a standardized approach to lighting and photographing the lesions, and standardized training. The study was grounded by theoretical frameworks that supported the design, methodology, and interpretation of findings. In particular, the study was grounded in sound measurement principles and psychometric theory. This study reports both the percent agreement ("raw" agreement) and statistics that account for chance agreement such as the kappa or intraclass correlation.

Limitations include that the study was conducted in a single setting and used a limited number of wound nurses (1 nurse expert and 9 wound/ET nurses). Each of the

wound nurse participants needed to observe multiple lesions. Mitigating factors are that this setting provides care to children from an eight-state region, that all wound/ET nurses were invited to participate, and that a large number of parents and bedside nurses were included in the sample.

The study used convenience, purposive sampling of peristomal lesions. Lesions can change rapidly (within hours), and for ratings to be comparable, all observers had to view the identical lesion. Therefore, all participants, including the parent, had to be present and available for data collection at the same time. This posed logistical challenges. However, all sequential cases that met inclusion criteria were enrolled in the study. The study only included participants who could speak and write the English language; therefore, the extent to which the instrument was feasible for use by non-English speakers was not assessed. The sample was predominantly Caucasian, as are the photos on the instrument, but it is possible that characteristics such as redness could be harder to distinguish and categorize on darker skin tones. However, the sample size was sufficiently large to allow robust statistical analyses and the demographics of the sample were representative of the patient population at this organization.

Implications

Peristomal skin lesions are common in children with stomas and can lead to repeat hospital visits, increased healthcare resource utilization, and diminished quality of life. The long-term goal is to improve patient outcomes and quality of nursing care for children with stomas in the inpatient, ambulatory, and home settings by developing methods for stoma management and prevention of peristomal skin lesions. Measurement and documentation are vital for managing peristomal skin lesions. However, clinical

documentation of peristomal skin lesions has been highly variable and the documentation can be difficult to locate within free-text notes. Aggregating information across patient records, or across published studies, can be challenging for researchers. There is a need to reduce variability in the measurement and documentation of peristomal skin lesions.

Caring for children with stomas at home can be challenging for parents. The study site (PCH) provides pediatric inpatient and outpatient services for patients from across the Intermountain West. Parents often call PCH wound care clinicians seeking advice on management of peristomal skin lesions after their child's hospital discharge. The parent is typically instructed to bring their child in for clinical evaluation, but quite often, the problem is minor and manageable by the parent at home. An instrument that can be used by both clinicians and parents is needed to support communication.

The SACS™ instrument was developed to help establish a standardized method of assessing and documenting the peristomal skin condition. The instrument has previously been evaluated for content validity, with stoma experts as the observers, based on data from adult stoma patients. The assessment showed high content validity with a few limitations noted by the observers (Beitz et al., 2010; Beitz & Ho, 2010). Although skin structure and physiology change with age, the skin assessment process is essentially the same for children and adults. Therefore, the previous content validity assessment is likely applicable in the pediatric setting.

This study adds to the knowledge base in several areas. It demonstrated the feasibility of SACS™ instrument's use in the pediatric setting. The study examined SACS™ instrument ratings based on both photographs and direct observations whereas the previous evaluations used only photographs. Previous literature only included stoma

experts. This study included a WOC nurse expert, other wound care nurses, bedside nurses, and parents as observers. Results of this study represent a first step for investigating the extent to which a standardized instrument could be used by parents and nurses to describe a child's peristomal skin condition. The same assessment instrument was usable by expert clinicians, nonexpert clinicians, and parents.

Previous literature focused on content validity. This study expanded the psychometric evaluation by examining reliability (both intrarater and interrater reliability) and multiple aspects of validity. Concept validity was supported by comments from the observers with a few limitations noted by the observers. Construct validity was supported by contrasted groups evaluations. Most importantly, the instrument showed high confidence when used to support the clinical decision of whether a lesion could be treated at home or needed to be observed in clinic (decision validity approach to construct validity).

Implications for Nursing Practice

Using the instrument to document the peristomal skin condition may facilitate communication between clinicians. The use of a standardized classification system can help provide a clear picture of prevalence and incidence rates as well as providing a way to monitor and report different types of peristomal skin lesions. The quality of nursing care provided to stoma patients can be enhanced by the use of evidence-based interventions. Care process models and stoma care algorithms designed to help clinicians make evidence-based decisions for peristomal skin lesions could be developed around SACS™ instrument ratings. A standardized classification system can provide a way to match interventions with peristomal skin lesions, thereby enhancing the practicability of

guidelines. Although the agreement for severity ratings was modest when comparing exact ratings, the high agreement when ratings were dichotomized around a clinically relevant threshold provides a means to evaluate interventions used in management and prevention of peristomal skin lesions.

The study examined the description of children's peristomal skin lesions by wound/ET nurses, bedside nurses, and parents using the SACS™ instrument. Having a standardized means of measuring peristomal skin lesions could enhance the home care experience. The patterns of rating correspondence were similar for parents and bedside nurses, suggesting that parents and nurses had similar understandings of the instrument definitions. An assessment tool that could be used by parents to describe the affected skin could help determine whether or not the child actually needs to come in to the clinic.

Implications for Nursing Informatics

The study has implications for nursing informatics practice as well. The Institute of Medicine (IOM) has developed a national vision for a learning healthcare system (LHS) that enables *virtuous cycles* in which evidence informs clinical care, and information from clinical care informs the growing body of evidence and knowledge. The LHS vision has become a national strategic objective, supporting federal incentive programs for meaningful use of health information technology. Informatics has been described as an essential, lynchpin component of the LHS vision (Cummins, 2014).

In order for patients and clinicians to make sound decisions, data must be able to be aggregated and communicated in a way that supports decision making. This requires standardization of data (Cummins, 2014). The nursing informatics (NI) specialty supports the achievement of the clinical goal by integrating nursing, computer, and information

sciences to examine issues related to a uniform terminology, structured care methodology, and technologic support (American Nurses Association., 2008; Cummins, 2014; Rolstad & Netsch, 2004). NI methods inform management and communication of data, information, and knowledge in stoma care nursing practice with the overall purpose of enhancing evidence-based practice and quality care for stoma patients (American Nurses Association., 2008; Rolstad & Netsch, 2004).

NI expertise is relevant for examining ways to document and communicate assessment findings (Cummins, 2014). Research in NI includes examining how information that supports nursing practice, including information used by patients and caregivers, is managed and communicated; and how that information supports decision-making (American Nurses Association, 2008; Cummins, 2014). Examining nursing documentation and standardized assessment tools is a recognized NI function. Examining the feasibility of using an instrument, a subset of human factors evaluation, is also a common role for informatics nurse scientists (American Nurses Association, 2008). Psychometric evaluation is an appropriate technique for nursing informatics scientists. Psychometric research examines the construction and/or evaluation of assessment instruments. Reliability and validity, which are core psychometric characteristics, are two of the most common measures of the quality of an assessment instrument. Other considerations may also affect judgment about the quality of an instrument for use within a given context, including cost, ease of use, feasibility, and acceptability. Nursing informatics practice is not separate from patient care; they are intertwined and NI practice fundamentally enables and supports clinical care (Cummins, 2014).

Future Work

Enhancements to the SACS™ Instrument

The SACS™ instrument could be enhanced to make it more useful. The instrument should incorporate more than one example of each lesion type to account for the variety of appearances that may be seen with a single type of lesion. Pictures of lesions on darker skin tone should also be incorporated into the tool. Simple terminology in lesion descriptions may also enhance the reliability of severity ratings, for example, "L1 – the skin looks red but not broken."

The instrument does not address the known or suspected cause for peristomal skin lesions such as chemical irritation, mechanical trauma, and disease- or infection-related causes such as yeast infection. The instrument rating is a summary assessment (e.g., of lesion severity) but does not record rich detail about precise aspects of the lesion (such as color, odor, or drainage). Clinicians will need to document these observations separately, which could be subject to the same variability currently seen in peristomal skin documentation. Adding a section that addresses suspected or known causes, or that allows for documentation of detail supporting the instrument rating, may enhance the tool's completeness.

An enhancement to the instrument would be to quantify the size of the affected skin area in addition to describing the location. This could be in standard measurement units (cm. or inches) or using percentages of skin under the barrier that is affected by the lesion. There may be some benefit in augmenting the SACS™ instrument location rating with a picture or graphic given the number of "partial match" location ratings. Almost all of the "no match" and "partial match" location ratings could be explained by a slight

rotation of the instrument. Occasionally, the difference was because a participant did not indicate a location. Adding body landmarks such as hip or umbilicus positions to the topographical location diagram might help improve the agreement about location ratings. Alternatively, the documentation of the lesion location might be enhanced with a drawing or picture of the lesion location in addition to the SACS™ instrument rating.

Future Research

Future studies should target the instrument's role in decision making such as determining whether the use of the instrument actually influences the advice to parents about the need to bring the child to the clinic. The effect of augmenting communication between nurses and parents using SACS™ instrument ratings, based on pictures sent by the parents, should be evaluated.

In addition, the instrument's role in the development of evidence-based care process models in the inpatient, ambulatory, and home settings should be explored. For example, current practice for lesions with granulation tissue (LX), regardless of the severity of erosive lesions, is to require clinical examination. There is some question among experts about whether that is actually necessary and this also may be a fruitful area for future research. Finally, the instrument should also be evaluated when used in patients with darker skin tones and across settings.

Conclusions

The SACS™ instrument was feasible for parents and nurses to use in the pediatric setting. There was evidence supporting instrument reliability and validity in this context, both when measurement was conducted based on direct observation and when it was

conducted based on pictures. To facilitate clinical decision making, meaningful categorization of the severity lesions based on clinically relevant thresholds is a more important consideration. When measurements were categorized into dichotomous groups, based on a clinically relevant threshold, both intrarater and interrater reliability metrics increased substantially. There was strong evidence of decision validity. The instrument was able to discriminate between lesions that needed to be seen in clinic and those that could be safely treated at home. When there was disagreement, the parents and bedside nurses tended to err on the side of safety, rating lesions as more severe than the expert, which would have resulted in the child being assessed in clinic by a wound expert. Therefore, it is safe and reasonable to conclude that the instrument can be used in the pediatric population to assess peristomal skin lesions and facilitate clinical decisions.

The instrument is simple with only three rating categories (severity of erosive lesions, presence/absence of granulation tissue, and lesion location). Thus it should be relatively straightforward to incorporate into electronic health records (EHRs) and personal health records (PHRs). This could form a basis for improved communications after the child is discharged.

The SACS™ instrument could be used as a form of standardized, structured documentation in the pediatric setting, perhaps augmented with a graphic or picture of the lesion with additional text as needed to provide rich detail. Adding a structured measurement to peristomal skin documentation would enhance the ability to use clinical documentation for quality improvement, evidence-based practice, and research purposes. Standardized documentation can help facilitate optimal patient care and give a clear picture into prevalence and incidence rates.

APPENDIX A

SACS™ INSTRUMENT

Teaching Guide

The SACS™ Instrument

Assessing and Classifying a Peristomal Skin Lesion

Content Validated[1]

Type of Lesion (L)

L1
Hyperemic Lesion
Peristomal redness with intact skin

L2
Erosive Lesion
Open lesion not extending into subcutaneous tissue; partial-thickness skin loss

L3
Ulcerative Lesion
Open lesion extending into subcutaneous tissue and below; full-thickness skin loss

L4
Ulcerative Lesion
Full-thickness skin loss with non-viable, dead tissue (necrotic, fibrinous)

LX
Proliferative Lesion
Abnormal growths present (ie, hyperplasia, granulomas, neoplasms)

Topographical Location (T)

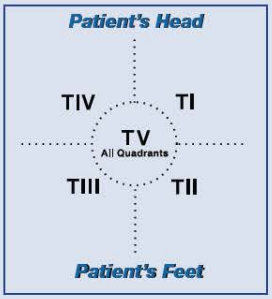
TI
Left Upper Peristomal Quadrant (12 to 3 o'clock)

TII
Left Lower Peristomal Quadrant (3 to 6 o'clock)

TIII
Right Lower Peristomal Quadrant (6 to 9 o'clock)

TIV
Right Upper Peristomal Quadrant (9 to 12 o'clock)

TV
All Peristomal Quadrants



SACS™ Classification Example

1. Beitz J, et al. Content validation of a standardized algorithm for ostomy care Ostomy Wound Manage. 2010 in press.

ConvaTec

SACS™ Instrument. Used with permission.

Rating Descriptions from the SACS™ instrument

Severity (L)	
Lesion	Description
Hyperemic lesion (L1)	Peristomal redness with intact skin
Erosive lesion (L2)	Open lesion not extending into subcutaneous tissue; partial-thickness skin loss
Ulcerative lesion (L3)	Open lesion extending into subcutaneous tissue and below; full-thickness skin loss
Ulcerative Lesion (L4)	Full-thickness skin loss with nonviable, dead tissue (necrotic, fibrinous)
Proliferative lesion (LX)	Abnormal growth present (hyperplasia, granulomas, neoplasms)
Topographical Location (T)	
Location	Description
TI	Left upper peristomal quadrant
TII	Left lower peristomal quadrant
TIII	Right lower peristomal quadrant
TIV	Right upper peristomal quadrant
TV	All peristomal quadrants

(Bosio et al., 2007)

APPENDIX B

SACS™ INSTRUMENT DATA RATING SHEET

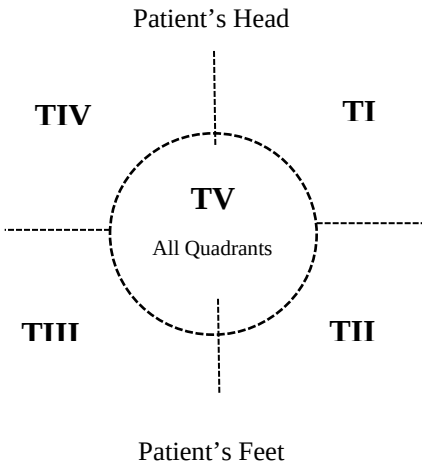
Participant #: _____ Patient #: _____

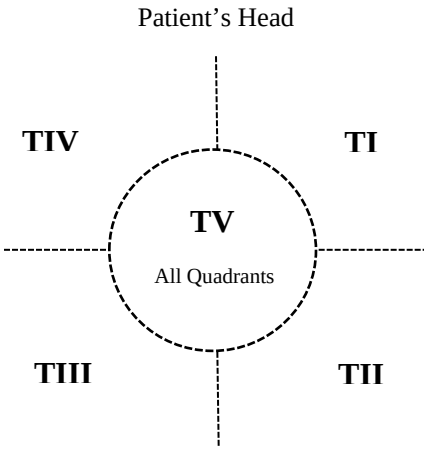
Please check mark your participant's Role:

WOC nurse expert	Wound/ET nurse	Bedside nurse	Parent/caregiver
	Is the RN WOC Certified? **Yes** ☐ **No** ☐		

Please rate the child's peristomal skin using the SACS™ Instrument

OSTOMY	G-TUBE
TYPE OF LESION (L)	**TYPE OF LESION (L)**
Please circle the type of lesion **L1 L2 L3 L4 LX**	***Please circle the type of lesion*** **L1 L2 L3 L4 LX**
TOPOGRAPHICAL LOCATION (T)	
Please circle the location or locations	***Please circle the location or locations***





I. How easy was it to use the SACS™ instrument?

1. Very easy
2. Easy
3. Neither easy or hard
4. Hard
5. Very hard

II. Did you find any part of the SACS™ instrument hard to use or figure out?

1. No
2. Yes

If **YES**, which part was hard or difficult to use or figure out?

APPENDIX C

DEMOGRAPHIC SURVEY

Participant #: _____

This section asks general questions about you. The information here will be summarized to describe who participated in the study. Please circle the choice that best describes you or fill in the blanks where indicated.

1. Which of the following best describes your role?
    a. Parent/primary caregiver of a child with a stoma
    b. Bedside nurse
    c. Wound/ET nurse – WOC certified
    d. Wound/ET nurse – not WOC certified

2. What is your gender?
    a. Female
    b. Male

3. What is your age?
    a. Less than 20 years
    b. 20 – 24 years
    c. 25 – 29 years
    d. 30 – 34 years
    e. 35 – 39 years
    f. 40 – 44 years
    g. 45 – 49 years
    h. 50 – 54 years
    i. 54 – 59 years
    j. 60 years and greater

4. What is your ethnic background?
    a. Hispanic, Latino, or Spanish Origin
    b. Not Hispanic or Latino

5. What is your racial background (select one or more)
    a. Asian
    b. Black or African American
    c. African
    d. Native Hawaiian or other Pacific Islander
    e. American Indian or Alaska Native
    f. White or Caucasian

6. What is your highest level of education?

a. Attended high school but did not graduate
b. High school Diploma/GED
c. Associate Degree
d. Bachelor's Degree
e. Graduate Degree
f. Other (Please specify) _____

The following question # 7 is for Wound/ET nurses and Bedside nurses ONLY.

7. How long have you been a nurse?
    a. Less than 6 months
    b. 6 months to 1 year
    c. 1 to 2 years
    d. 3 to 4 years
    e. 5 to 6 years
    f. 7 to 8 years
    g. 9 to 10 years
    h. 11 years and greater

THIS SECTION IS FOR PARENTS/CAREGIVERS ONLY

This section asks about technology that you have at home. Please circle the choice that best describes your answer, or fill in the blanks where indicated.

1. Do you have Internet access at home?
    a. Yes b. No

2. Do own a digital camera?
    a. No
    b. Yes. If YES, can you email pictures that you took with your digital camera?
        i. Yes ii. No

3. Do you own a cell phone that has a camera?
    a. No
    b. Yes. If YES, can you text or email photographs that you took with your phone?
        i. Yes ii. No

4. Would you be willing to communicate with a wound/stoma care nurse using email or text messaging, if asked to do so?
    a. Yes, EMAIL only

b. Yes, TEXT messaging only
c. Yes, either EMAIL or TEXT messaging
d. No

5. Would you be willing to send pictures to a wound/stoma care nurse using email or text messaging, if asked to do so?
    a. Yes, EMAIL only
    b. Yes, TEXT messaging only
    c. Yes, either EMAIL or TEXT messaging
    d. No

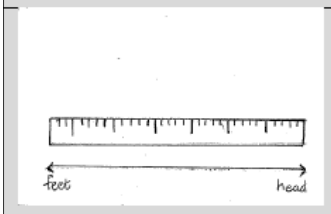
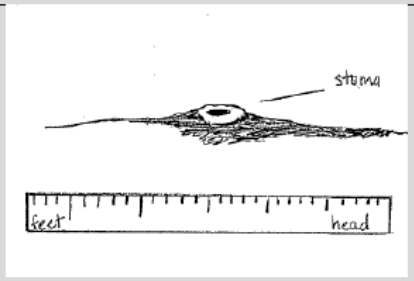
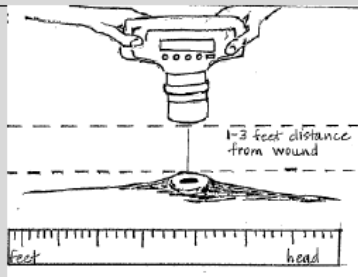
6. After your child goes home and you needed to talk with the wound/stoma nurse about your child's stoma. Would you be willing to rate your child's stoma using the SACS^{TM} instrument while at home?
    a. Yes
    b. No. Please tell us why _____

7. How hard do you think it would be to rate your child's stoma at home using the SACS^{TM} instrument?
    1. Very easy
    2. Easy
    3. Neither easy or hard
    4. Hard
    5. Very hard

APPENDIX D

PERISTOMAL SKIN PHOTOGRAPHY PROTOCOL

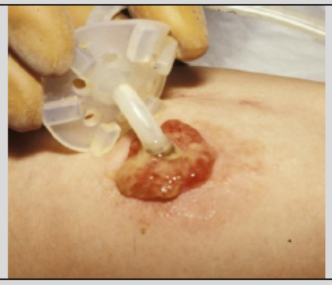
1. Expose the peristomal skin by removing all dressings, stoma pouch, and skin barrier/wafer
2. Cleanse the peristomal skin where appropriate using normal saline

3. Write the words "head" on one end of a disposable ruler and "feet" on the opposite end	4. Place the disposable ruler on the healthy skin next to the stoma (do not place over affected skin) with "patient's head" pointing towards the patient's head and "patient's feet" toward the feet	5. Photograph the entire peristomal skin to include the stoma, healthy skin, surrounding cellulites, and disposable ruler.
		

6. Upload image into secure database with pertinent information (patient study ID, location, type of stoma, etc).

SAMPLE PHOTOGRAPHS

Gastrostomies with feeding tubes


Ostomies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